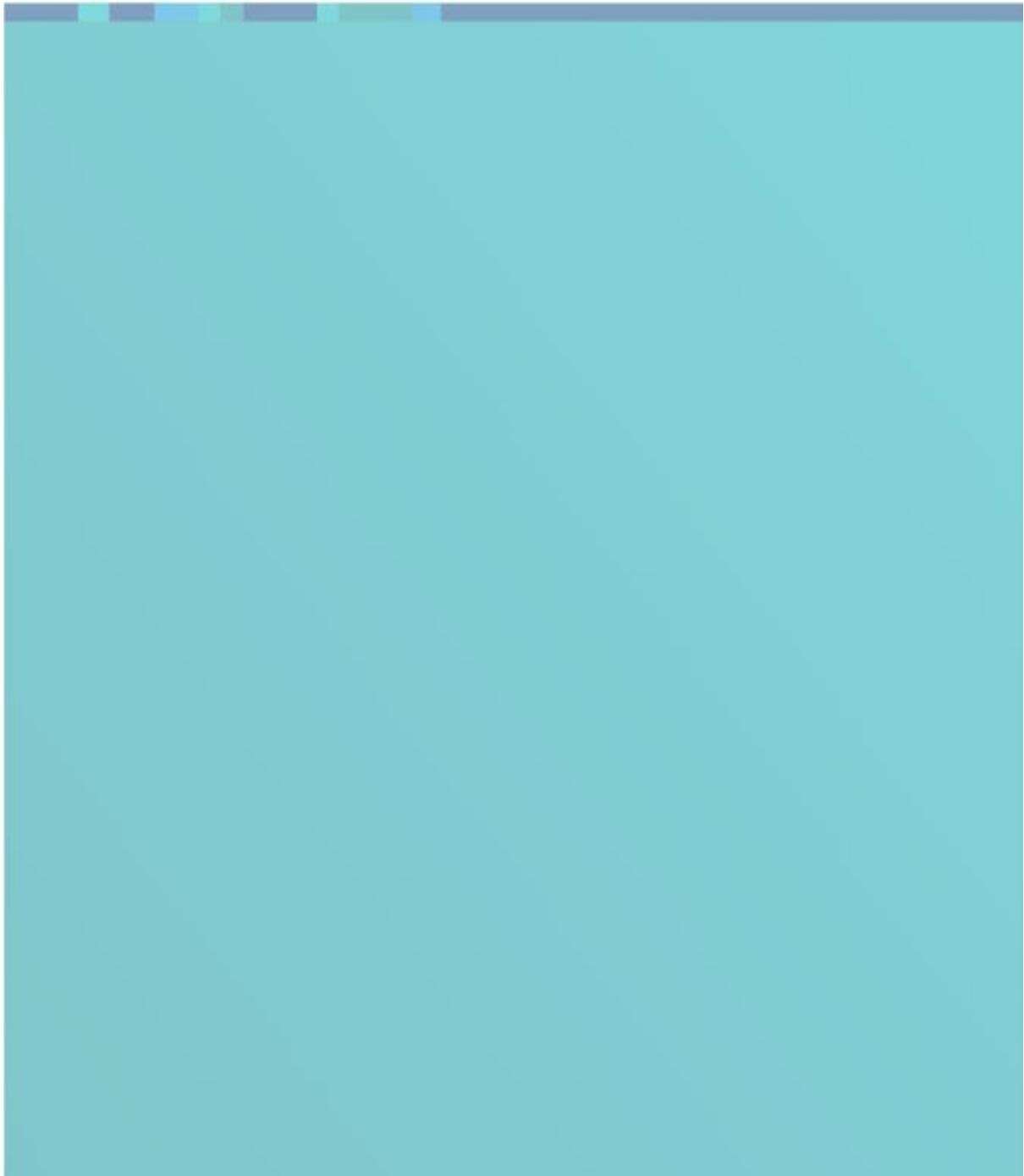




Australian Government
**Department of Health
and Aged Care**

National Medicines Policy 2022



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Australia's National Medicines Policy

Introduction

Australia's National Medicines Policy (NMP) is a high-level framework focused on the availability and the use of medicines and medicines-related services. The NMP relates to medicines research and development, manufacture, regulation, evaluation, supply, dispensing, storage and access. It promotes the quality use of medicines and medicines safety by focusing on the current and future health needs of people and the responsibilities of all partners to achieve the best health, social and economic outcomes for all Australians.

The NMP identifies and brings together all partners around a common aim and a shared responsibility for policy stewardship. The NMP acknowledges the fundamental role of consumers in achieving the policy aim by placing the individual at the centre, and by focusing on and responding to the needs of Australia's diverse population.

The success of the NMP relies upon shared decision-making, strategic partnerships and the involvement of people with lived experience in the co-design, development, implementation and evaluation of related policies, strategies, programs and initiatives.

The NMP influences, and is influenced by, other related policies, strategies, legislation, programs and initiatives across Australia's health, social and economic systems. Achieving the NMP's vision and aim requires close alignment with key areas of health reform in Australia and action across Ministerial portfolios and Australian, state and territory levels of government.

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

Vision

To achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment.

This vision can be realised through effective partnerships, structures and processes with defined responsibilities to support the NMP.

Aim

The aim of the NMP is to ensure:

- Equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines and medicines-related services for all Australians.
- Medicines are used safely, optimally and judiciously, with a focus on informed choice and well-coordinated person-centred care.
- Support for a positive and sustainable policy environment to drive world-class innovation and research, including translational research, and the successful development of medicines and medicines-related services in Australia.

Scope

In the NMP context the term 'medicines' covers a broad range of therapeutic options, products and interventions used to prevent, treat, monitor, manage or cure a disease or health condition. This encompasses prescription medicines, including biologic and non-biologic medicines, gene therapies, cell and tissue engineered medicines and vaccines, non-prescription medicines, complementary medicines, and traditional medicines, including Aboriginal and Torres Strait Islander traditional medicines.

Devices used to administer and monitor the response to medicines, or in combination with medicines, are also included within the NMP's scope.

The term 'medicines-related services' includes services and programs that support the quality use of medicines and medicines safety, for example, education, training and awareness programs, digital information and clinical decision support systems, medication review services, and diagnostic services including for personalised medicines.

The NMP uses terms, principles and concepts from related policy and operational contexts, and recognises these will evolve over time. For example, the Central Pillars and Principles uses terms that are aligned with and are intended to be consistent with national quality use of medicines guiding principles for medication management.

This broad scope means the NMP is positioned to adapt and respond to:

- new and emerging treatments and technologies
- new or improved medicines-related services
- any future policies developed for devices or other technologies
- ongoing enhancements to Australia’s therapeutic goods regulatory framework
- ongoing improvements to national coordinating arrangements for safety and quality in health care.

Achieving the vision and aim through partnerships

Partners to the NMP include individuals, families and carers, the Commonwealth, state and territory governments and regulatory agencies, non-government organisations, health practitioners, consumer organisations, including not-for-profits, the private and public health sectors, industry (including pharmaceutical, software and medical service delivery industries), researchers and academics, health educators, including higher education and professional training bodies, health professional organisations and other health related agencies, the media, and the general community.

All partners must be engaged in a collaborative, cooperative manner to achieve the best health, social and economic outcomes for all Australians. Each partner has a role in progressing the NMP through demonstrating respect for and recognising the expertise and contribution of other partners, with some partners also having additional responsibilities so the NMP’s objectives can be achieved. (Figure 1).

Figure 1 – Centrality of individuals, carers, families and communities, and the relationships between the NMP partners



Central pillars, principles and enablers

The NMP is founded on four interconnected central pillars, which together with principles and enablers, are fundamental to the achievement of the vision and aim of the NMP (Figure 2). The Policy sets out the responsibility of all partners to work collaboratively, cooperatively and transparently to achieve its aim and the intended outcomes of each of the central pillars.

Figure 2 – Overview of the NMP

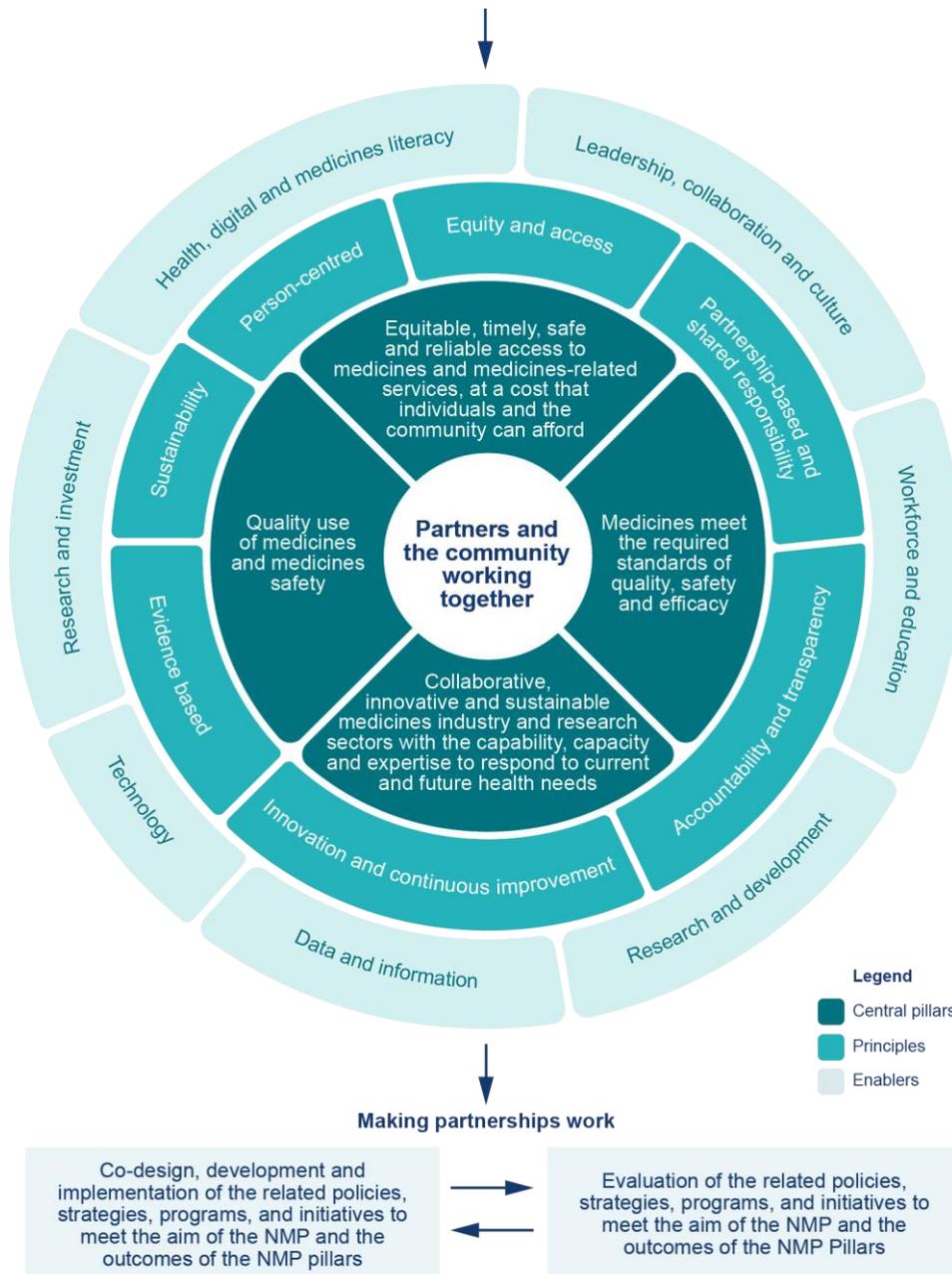
Vision

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Aim

To ensure:

- Equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines and medicines-related services for all Australians.
- Medicines are used optimally and judiciously, with a focus on informed choice and well-coordinated person-centred care.
- Support for a positive and sustainable policy environment to drive world-class innovation and research, including transnational research, and the successful development of medicines and medicines-related services in Australia.



Central pillars

The central pillars of the NMP are:

- equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford
- medicines meet the required standards of quality, safety and efficacy
- quality use of medicines and medicines safety
- collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.

The NMP identifies the intended outcomes associated with each of the central pillars.

Principles

The NMP identifies a set of fundamental principles intended to guide and direct all partners to work collaboratively, cooperatively and transparently in achieving the NMP's aim through the co-design and development, implementation and evaluation of its related policies, strategies, programs and initiatives.

Principle	Principle in action
Person-centred	Consumers are supported and enabled to be well informed and active participants in all decision-making, acknowledging their aspirations, diversity and lived experience. This includes developing and building health, digital and medicines literacy so that individuals, carers and families, and the broader community are well informed and active participants in decision-making. Individuals, their families and/or carers are supported to be involved at all levels of the NMP, including in the co-design and development, implementation and evaluation of its related policies, strategies, programs and initiatives.
Equity and access	All actions relating to the NMP focus on delivering and achieving positive health outcomes that matter most to people and their communities. All Australians have timely, safe and reliable access to effective, high-quality medicines and/or other appropriate management options, culturally safe medicines-related services and culturally safe medicines-related information. Access is irrespective of diversity, background, age, disability, location or personal circumstance. The NMP's focus is on delivering positive ways to eliminate health inequities that are experienced by vulnerable population groups within the community. These groups include Aboriginal and Torres Strait Islander people; people from culturally and linguistically diverse backgrounds; children and older people; people with disability; people living in rural and remote areas; people of low socioeconomic status; people living with rare and under-recognised diseases; people with mental illness; lesbian, gay, bisexual, transgender, queer or questioning, intersex and/or other sexuality and gender diverse people (LGBTQI+); and other vulnerable population groups including pregnant and breastfeeding women. People may identify as belonging to one or more of these population groups and, as such, may have compounding health and wellbeing experiences that must be considered.
Partnership-based and shared responsibility	Active, respectful dialogue, collaboration and cooperation is established and maintained between partners - listening to and recognising the wisdom and expertise of each partner. All partners act responsibly, as stewards of the NMP.
Accountability and transparency	All partners accept responsibility for their actions and are held accountable for advancing the progress of the NMP's central pillars. All activities are undertaken, and information shared, in a respectful, ethical and transparent way.
Innovation and continuous improvement	All partners proactively support new and improved ways to identify and respond to current and future health needs, and deliver greater value to achieve the best health, social and economic outcomes for all Australians. This includes reducing inequities across society and continually improving the health system, with a particular focus on medicines and medicines-related services.

Principle	Principle in action
Evidence-based	All partners apply relevant, current and context-specific evidence and consensus best practice to guide collaborative research, decision-making, program design and communication. This includes information on safety, efficacy and effectiveness, and both real-world experience and patient reported experience and outcomes.
Sustainability	All partners focus on optimising medicines use and considering the health, social and economic impact and sustainability of the strategies, policies, programs or initiatives they deliver or fund. All partners work to protect and reduce the impact on the natural environment from the research, development, manufacture and supply of medicines, and delivery of medicines-related services. This includes the safe collection and segregation of, and appropriate and secure disposal of, expired or unwanted medicines, devices and medicines packaging, ensuring minimal impact on the environment.

Enablers

Seven enablers are critical to the success of the NMP:

- **Health, digital and medicines literacy** – to build the skills, knowledge, understanding, motivation, capacity and confidence of a person to access, understand and use information to make well informed decisions about their health and health care, including using medicines safely and effectively. The whole health system must respond to an individual's health and medicines literacy needs, by delivering person-centred health information, education, support and services. The way information is developed must be appropriate to each person's culture and language, health beliefs, accessibility, disability and information needs. Digital tools and technologies must be used to help and empower people manage their health and wellbeing, connect them in meaningful ways to their health care teams and offer them choices for how, when and where care is delivered.
- **Leadership, collaboration and culture** – to encourage a commitment by all partners to the NMP to identify, pursue and communicate the aim, pillars and principles in a collaborative, consultative, respectful, flexible, adaptable and transparent manner. All partners must develop, support and promote a culture that is open to creativity, learning and quality improvement, including through co-design and other participatory approaches.
- **Workforce and education** – to ensure a workforce that is knowledgeable, capable, competent, accessible and resourced to provide well-coordinated, integrated and person-centred care. Health professionals are appropriately trained to work to their full scope of practice, consistently across all jurisdictions within Australia, in collaboration with other partners, and apply relevant and current best practice guidelines.
- **Research and development** – to deepen knowledge and facilitate innovation and delivery of equitable, safe access to new and better medicines, and new and improved medicines-related services to maintain good health, reduce harm and inform continuous improvement in the quality use of medicines and medicines safety. This includes supporting international research collaboration through partnership and policy.
- **Data and information** – to ensure the responsible collection, secure storage, appropriate use, management and sharing of data and information. Data driven insights and digital integration enables evidence-based decisions to improve health outcomes, equity and access, the quality use of medicines, medicines safety and health system efficiency. This includes the capability of horizon scanning to use and translate data in predicting future trends, including medicine use, emerging disruptive and innovative therapies, and transformative technologies.
- **Technology** – to embrace and adopt digital information and technologies, and methods that are validated and interoperable to promote efficient continuity of medicines management activities and drive improvements in access, quality, safety and efficiencies for all Australians across their health journey and use of medicines.
- **Resources and investment** – to ensure appropriate and adequate resources are sustainably invested, distributed, and equitably, effectively and efficiently used, to achieve the aim of the NMP through each enabler.

Pillar 1: Equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford

Intended outcome

- **Medicines and medicines-related services are affordable and accessible in an equitable, timely and safe manner, leading to the achievement of the best health, social and economic benefits for all Australians.**

Ensuring equity of access to medicines and medicines-related services for all Australians involves considering timeliness, safety, affordability and the health, social and economic benefits. National programs that provide subsidised access to medicines include but are not limited to the Pharmaceutical Benefits Scheme (PBS), Repatriation Pharmaceutical Benefits Scheme (RPBS), and the National Immunisation Program (NIP). Medicines are also accessed through public and private hospitals, clinical trials, compassionate access programs, or privately purchased (including non-prescription medicines). This is supported by access arrangements between federal, state and territory governments for certain technologies.

Equity

Irrespective of diversity, background, age, disability, location or personal circumstance, all Australians should have equitable access to safe, effective and high-quality medicines, culturally appropriate medicines-related services and medicines-related information.

This pillar focuses on eliminating health inequities that may be experienced by vulnerable population groups, as outlined in the principle of 'Equity and access'. Specific examples of issues experienced by vulnerable population groups that NMP partners need to consider and address include:

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

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

Timeliness

All Australians, regardless of where they live, who they are and the health condition they have, must have timely, safe and reliable access to effective medicines and medicines-related services to maintain their health and wellbeing at a world class level. Appropriate and efficient processes must exist for the evaluation of risk-benefit, value and subsidisation of medicines to ensure optimal access for Australians. This includes the flexibility to rapidly respond to emerging and disruptive technologies, including innovative and highly specialised therapies and services, especially in circumstances where individuals have high unmet clinical needs or in response to public health emergencies or natural disasters. These processes and their outcomes need to be effectively communicated to all stakeholders, including to the public, to build and maintain community understanding and confidence. Further, processes finalising the financing, price, economic and supply arrangements of medicines must be efficient to secure access in an optimal manner. Safety and quality are described in detail under Pillars 2 and 3.

Timeliness has several other contexts and barriers for individuals, their families and/or carers, including not being able to access medicines and medicines-related services due to shortages or other supply challenges, particularly for rural and remote communities. This requires all partners to commit to working together openly and transparently and to take action to reduce the risk, and minimise the impact of, medicines shortages and other supply challenges.

Affordability and value-based health care

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

A robust and transparent mechanism for determining the value of a medicine by governments and other payers is essential for the coordinated, fair and efficient supply and use of medicines. The value of a medicine includes benefits to the health and wellbeing of the individual, the social and economic benefits to the individual, their families and/or carers, as well as to the broader society.

Initial and continued investment decisions should be informed by rigorous health technology evaluation. This includes incorporating real-world evidence, patient reported outcomes and the potential impact of a medicine across Australia's broader health systems, where appropriate.

Pillar 2: Medicines meet the required standards of quality, safety and efficacy

Intended outcomes:

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

All medicines supplied in Australia are regulated by the Therapeutic Goods Administration (TGA). This includes prescription, non-prescription and complementary medicines.

No medicine is 100 per cent risk-free, and the risk is greater for some medicines. The TGA takes a risk-based approach to regulation with more rigorous controls on medicines that pose a higher risk when used or misused. The TGA assesses the quality and safety of all medicines, as well as the efficacy of those medicines posing a higher risk. The TGA also regulates the manufacturing and advertising of medicines, as well as whether a valid prescription and/or consultation from a health professional is required for access by consumers.

Protecting the health and safety of the community

Ensuring the safe and quality use of medicines is fundamental throughout the medication management pathway and consumer journey, including at transition of care. For medicines that pose a higher risk, ongoing quality assurance processes guarantee the highest standards of quality, safety and efficacy are met for specific medical conditions or indications.

These processes include assessments both before and after a medicine is registered with input from individuals, their families and carers and health professionals. The outcomes of these assessments are generally made available to the public. This promotes transparency and shows how quality, safety and efficacy standards are achieved and maintained.

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

- improve access to up-to-date, easily understood, evidence-based information to help people make informed health care decisions, including whether to take a medicine or choose other management options.
- build the Australian public's knowledge about medicines regulation, including the expectations and limitations of medicines regulation.
- facilitate and encourage effective reporting of adverse events by individuals, families and carers, and health professionals to support the safe and quality use of medicines.
- assist in identifying and reporting potential issues with medicines use or misuse, and quality, safety and efficacy.
- ensure all suppliers, researchers and industry understand and meet their requirements as outlined in relevant codes of conduct and legislation.

Effective, timely and risk-proportionate regulation

Australia's medicines regulatory system protects the health and safety of the community by being up-to-date, flexible and supporting timely, safe access to innovative, evidence-based medicines and medicines-related services.

This can be achieved through:

- Rational, standardised and transparent criteria and processes to evaluate and monitor medicines.
- Pursuing opportunities to collaborate with recognised international regulatory agencies to facilitate a standardised approach, reduce unnecessary duplication and facilitate earlier access to medicines for all Australians.
- Regulations that ensure appropriate and ethical practices are followed in the research, development, evaluation, manufacture, supply, storage and advertising of medicines.
- Regulations to reduce diversion of counterfeit medicines into the Australian supply chain.
- Regulations and communication to reduce the risks associated with unregulated herbal/supplemental medicinal products.
- Clear and transparent processes for responding to regulatory problems or breaches quickly and proportionately, including communicating the outcomes to all partners and affected individuals.
- Ensuring evidence-based, accurate and easily understood medicines-related information is available to all individuals, families and carers and health professionals.
- Developing and implementing flexible and adaptable processes, where appropriate, to respond to high unmet clinical need, medicines supply challenges, public health emergencies and natural disasters.
- Building positive, cooperative and collaborative relationships between regulators and the medicines industry, research sector, individuals, families and carers, and health professionals, using effective models for co-regulation where appropriate. This includes Commonwealth and state and territory arrangements to protect the Australian public from false or misleading advertising of products and services.

Pillar 3: Quality use of medicines and medicines safety

Intended outcomes:

- **Individuals, their families and/or carers are empowered to actively participate in shared decision-making in relation to the safe and quality use of medicines and medicines-related services in the prevention, management and treatment of a specific health condition or indication and for the maintenance of good health.**
- **Adopting a person-centred approach, health professionals commit to, are trained and proactively supported to implement programs and initiatives to achieve the safe and quality use of medicines.**

The Australian Commission on Safety and Quality in Health Care (ACSQHC) leads and coordinates national improvements in the safety and quality of health care to improve value and sustainability in the health system. ACSQHC complements the regulatory role of the TGA to achieve better health outcomes and experiences for all individuals, their carers and/or families. This includes initiatives to reduce medication errors and harm from medicines to improve the safe and quality use of medicines in Australia.

The quality use of medicines and medicines safety is integral to the NMP and is a National Health Priority. This includes:

- **Selecting treatment options** – medicines may be chosen to manage health conditions and treat illnesses. Medicines must only be chosen where they offer the most appropriate alternative to self-care, prevention and other management or therapeutic options, which must be considered and accessible.
- **Choosing suitable medicines** – in selecting, prescribing or deprescribing a medicine, the clinical and non-clinical factors, individual's experience, needs, preferences and values, potential benefits and harms, and the out-of-pocket cost of access, must be considered.
- **Using medicines safely and effectively** – getting the best possible results means monitoring outcomes, reporting adverse events, managing symptoms or side effects, minimising misuse, overuse and underuse, and empowering and supporting people to make decisions to use medicines safely and effectively.

Quality use of medicines and medicines safety includes medicines management. This includes but is not limited to information and decision support tools in clinical decision-making, compliance and safety in medicines distribution and storage systems, targeting known risk areas, work practices such as standardisation, monitoring and risk assessment and using medication safety strategies and tools to create an environment for the best communication of medicine-related information.

Person-centred care and shared decision-making improve health outcomes and the safe and quality use of medicines

Person-centred care, including information that supports shared decision-making and the right to make choices, is essential for the quality use of medicines and medicines safety. Health literacy, digital literacy and specifically medicines literacy help people to decide, with their health professional, whether to use a medicine.

Medicines literacy means people know how to find and use medicines-related information that is relevant, accurate and meaningful to them.

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

- encourage individuals with their families and/or carers to be active, empowered and informed participants in shared decision-making.
- support and empower individuals, their families and/or carers to attain medicines literacy to allow full participation in decisions around medicines as equal partners with health professionals.
- embrace wisdom and experiences of individuals, their families and/or carers in a shared decision-making partnership with health professionals.
- encourage people to ask for and use objective, evidence-based, trusted, reliable and good quality information, resources, and services as part of a shared approach to informed decision-making.
- develop the skills and confidence of people to manage their own health and medicines, including when and where to get help, when needed.
- provide individuals, their families and/or carers and health professionals with access to clear, consistent, standardised, timely, objective, credible, up-to-date information on medicines use appropriate to their needs. Including for use in particular patient populations, for example, medicines used during pregnancy and breastfeeding.
- provide culturally safe, person-centred services and support for both face-to-face and non face-to-face interactions.
- provide prompt, appropriate, targeted and tailored support for people to understand the risks and benefits of medicines and the role of other options to achieve the best health outcomes.

The NMP recognises that people with low health literacy, including low medicines literacy, are less well equipped to prevent and manage illness and maintain good health. The safe and quality use of medicines must be available to individuals, their families and carers with diverse language skills and cultural backgrounds. All Australians must be involved in the co-design, implementation and evaluation of medicines use and medicines-related services.

All NMP partners recognise that focusing on health, digital and medicines literacy is not limited to supporting the safe and quality use of medicines. It contributes to positive outcomes for health system engagement over a lifetime.

All health professionals have responsibility for supporting safe and quality use of medicines in interactions with individuals by supporting the up-to-date list of medicines as confirmed by the individual, their families and/or carers. Any changes to the medicines list as part of shared decision making are to be communicated to the individual, their families and/or carers and with all health professionals involved in their care.

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

Reducing harm and promoting the safe and best possible use of medicines is a continuous process. It requires health professionals to be up-to-date with the development and appropriate use of existing and emerging medicines and health technologies. Medicines – whether prescribed, recommended or self-selected – should only be used when clinically appropriate, in accordance with best practice. Health professionals must be trained in person-centred care and informed decision-making to enable discussions on treatment options, including medicines, as part of their care.

Collaborative efforts by all partners to minimise the risk of harm from the use, overuse, underuse and misuse of medicines is crucial. Specific examples include:

- actively monitoring people for early signs and symptoms of medicine harm or misuse.
- actively asking people who have started a new medicine about any symptoms or side effects they are experiencing.

- appropriate use of antimicrobials (including antibiotics, antivirals, antifungal and antiparasitic agents) to reduce antimicrobial resistance.
- monitoring and responding to inappropriate polypharmacy (the use of multiple drugs).
- deprescribing (ceasing) unnecessary medicines.
- reducing harm from high-risk medicines.
- improving the safe and quality use of medicines at transitions of care and in all settings, including through effective information transfer and medication reconciliation and review where appropriate.

Medicines are an important element of almost every type of care and are the most common form of healthcare intervention. NMP partners recognise that supporting individuals, their families and/or carers and health professionals and the health system in the safe and quality use of medicines requires:

- leadership that builds a culture of coordination and collaboration of programs, initiatives and support.
- guidance including policies, guidelines, accreditation standards and clinical information systems that guide the safe and quality use of medicines. This requires increasing the effectiveness and interoperability of digital systems and the use of smart technologies.
- education, training and awareness campaigns to support health professionals to safely prescribe, dispense and administer medicines, monitor their effects, deprescribe when necessary, and engage people in decision-making about their use of medicines.
- access to up-to-date, evidence-based, trusted, reliable and good quality information relevant to the Australian health system. This includes access to medicines-related information across the full medication management pathway and healthcare journey, and which addresses misinformation and the unethical promotion of medicines.
- research, evaluation and efficient data collection, to monitor, analyse and report on outcomes to improve the quality use of medicines and medicines safety.

Pillar 4: Collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs

Intended outcomes:

- **Thriving, dynamic medicines industry and research sectors that are proactively supported to contribute to meeting current and future health needs in Australia and internationally. The sectors work within a positive, sustainable and responsive policy environment that delivers and promotes world-class innovation, including encouraging the development and commercialisation of medicines, new technologies and related services.**
- **A diverse medical research sector that generates high-quality evidence, strategies, systems and processes, which support ongoing improvements in the quality use of medicines and medicines safety.**
- **Collaborative, robust, efficient, and reliable supply chains and networks that deliver equitable, timely, affordable and safe access to medicines and medicines-related services throughout Australia.**

The medicines industry and research sectors contribute significantly to enhancing health outcomes and creating social and economic value in Australia. Collaborative, dynamic and sustainable medicines industry and research sectors are critical to ensuring all Australians can benefit from their innovations. The supply chains and networks for medicines and devices that are in scope of the NMP include: product sponsors; manufacturers; wholesalers, health software providers, hospitals; community and hospital pharmacies; Aboriginal Health Services; residential aged care facilities; and all other delivery settings.

The NMP commits all partners to coordinating and aligning service delivery and health, research, education and industry policy.

A supportive and collaborative medicines industry and research environment

The medicines industry and research sectors must be supported by strategic investment together with effective industry, education and research policies of governments, driving strong partnerships between academia, government science organisations, industry, health services and individuals, their families and/or carers. The Australian medicines industry and the research sectors must be able to operate with confidence in a global environment to further enhance international competitiveness. Promoting agreed international standards for the protection of intellectual property rights can help underpin trade and investment and enable innovation and creativity.

All partners should continuously aim to improve and develop research knowledge, capabilities, processes and infrastructure to expand the clinical trials sector in Australia.

Efficient, effective processes and systems that encourage and support innovation, evaluation and access are required. Regulatory and access processes should be fit-for-purpose and aligned with international best practices, to ensure protection of patient safety and robust, evidence-based outcomes.

With the aim of building reliable and integrated supply chains and networks, there should be a focus on and commitment to support and encourage the development of advanced manufacturing capabilities for biopharma and medical technologies. This can be achieved by increasing investment in infrastructure and commercialisation, supporting strategic partnerships, innovation hubs and driving the translation of innovative research outcomes.

Effective collaboration between governments, healthcare professionals, industry, researchers and educators are needed so that all Australians can access medicines that deliver health improvements, and to realise the social and economic benefits that come from innovation.

Partnerships – achieving the NMP’s vision and aim

All partners need to play their role in progressing the NMP, in a manner that is respectful of the interrelationships and expertise of other partners. Conflicts of interest are to be declared by all partners and appropriately managed.

All partners are encouraged to map out the areas where they can deliver and/or influence the achievement of the NMP’s vision, aim and outcomes.

The role of the Commonwealth, state and territory governments, as well as other partners, is to facilitate, coordinate and monitor the progress towards the attainment of the NMP’s aim through transparent evaluation and reporting mechanisms. This requires partners to communicate how the principles of the NMP are being actioned in practice and how their actions address, deliver and achieve the outcomes of the NMP’s pillars. This information is to be reported in an easy to understand and meaningful way, be accessible and continually updated through progress reporting.

It is recognised that different partners, or groups of partners, bear responsibility for the intended outcomes of each pillar of the Policy. The supporting activities of other national health strategies are to be considered to ensure that the NMP is implemented in a considered, consistent and integrated way.

Making the partnership work

To achieve the intended outcomes of the central pillars, all partners, in line with the NMP’s principles, must work together collaboratively, cooperatively and be respectful of the expertise of each other.

Pillar 1 – Equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford

To achieve the intended outcome of Pillar 1, the following partners have primary responsibility for ensuring timely, equitable and reliable access to medicines, at a cost that individuals and the community can afford.

Partners and their broad responsibilities and functions to advance Pillar 1

Intended outcome	Partner	Broad responsibilities and functions
Medicines and medicines-related services are affordable and accessible in an equitable, timely and safe manner, leading to the achievement of the best health, social and economic benefits for all Australians.	Consumer organisations and representatives, patient advocates, not-for-profits	Support and advocate for engagement by individuals, their families and/or carers with participation in the health sector at the individual, service and system levels. Support and be involved in the development and distribution of health and evidence-based medicines information for individuals and groups, particularly those who may experience inequity of access or different/additional challenges to accessing medicines.
	Health professionals	Consider and discuss treatment options and appropriately recommend, prescribe, dispense or supply medicines and medicines-related services, applying a person-centred approach to help people decide whether to use a medicine, and to promote the quality use of medicines and medicines safety.

Intended outcome	Partner	Broad responsibilities and functions
	Commonwealth government and national agencies	<p>Deliver national health programs and regulatory functions that ensure equitable, timely, affordable, safe and reliable access to medicines and medicines-related services.</p> <p>Be accountable for proactive engagement and alignment across partner jurisdictions, ensuring the interoperability of systems, policies and procedures.</p> <p>Support nationally consistent platforms, governance, processes and guidelines for a safe, accessible, active and progressive clinical trial sector.</p>
	State and territory governments and agencies	<p>Deliver safe, reliable access to equitable and affordable medicines through publicly funded services.</p> <p>Be accountable for proactive engagement and alignment across partner jurisdictions, ensuring interoperability of systems, policies and procedures and clinical trial governance.</p>
	Medicines industry, including software providers	<p>Research, develop and supply medicines that provide the best health and socioeconomic value to the individual and the community, in an equitable, timely and sustainable way.</p> <p>Provide consistent and standardised medicines-related information to health professionals and individuals, their families and/or carers.</p>
	Researchers	<p>Lead research and clinical trials, consistent with national and international guidance, that contribute evidence supporting the safe, timely, equitable and reliable access to medicines and medicines-related services.</p>
	Health educators, including higher education and professional training bodies	<p>Work constructively and transparently with all partners to develop and deliver educational curricular and training programs that support equitable, timely and safe access to medicines and medicines-related services for all Australians.</p>
	Health professional organisations and other health related entities	<p>Develop and support systems, processes and guidelines, which promote the safe, timely, equitable and reliable access to medicines.</p>
	Media	<p>Report responsibly on issues relating to the safe, timely, equitable, reliable and affordable access to medicines.</p>

Pillar 2 - Medicines meet the required standards of quality, safety and efficacy

To achieve the intended outcomes of Pillar 2, the following partners have primary responsibility for effective medicines registration and scheduling processes.

Partners and their broad responsibilities and functions to advance Pillar 2

Intended outcomes	Partner	Broad responsibilities and functions
<p>Australia's medicines regulatory processes are efficient, protect health and safety and are trusted by the community.</p> <p>Medicines are safe and effective, and their labelling and supporting information is readily available and supports the quality and safe use of medicines.</p>	<p>Consumer organisations and representatives, patient advocates, not-for-profits</p> <p>Individuals, their families and/or carers</p>	<p>Promote and facilitate involvement of individuals, their families and/or carers in the approval of medicines and the monitoring and reporting of adverse events or product quality issues.</p> <p>Engage and promote an understanding of the medicines regulatory system and facilitate consumer involvement into evidence-based medicines information to support the effective, safe and quality use of medicines.</p>
	Health professionals	<p>Prescribe, dispense, supply or administer medicines in line with relevant guidelines, and in consultation with the person taking the medicine, or their families and/or carers.</p> <p>Commit to contributing to coordinated pharmacovigilance programs including by monitoring and reporting adverse events and medicines safety issues in clinical practice.</p>
	<p>Commonwealth government and national agencies</p> <p>State and territory governments and agencies</p>	<p>Work collaboratively and consistently to achieve best practice, responsive and relevant regulation for the research, development, production, supply and advertising of medicines.</p> <p>Ensure international relevance and alignment, where appropriate.</p> <p>Ensure best practice communication in medicines-related information, including labelling, product information and consumer medicines information.</p>
	<p>Researchers and medicines industry, including software providers</p>	<p>Adhere to relevant research and development, manufacturing and regulatory standards, including post-marketing safety monitoring and reporting.</p> <p>Ensure appropriate language in the development and review of easy-to-understand, accurate, consistent and standardised medicines-related information for individuals, their families and/or carers and health professionals.</p>

Intended outcomes	Partner	Broad responsibilities and functions
	Professional organisations	Promote best practice in reporting adverse events or other medicines-related issues to appropriate authorities.
	Health educators, including higher education and professional training bodies	Develop and deliver training modules on the regulatory function, processes, operation and the role of partners in supporting data collection on the safety, quality and efficacy of medicines.
	Media	Responsibly and accurately inform the public about product safety and quality issues.

Pillar 3 - Quality use of medicines and medicines safety

To achieve the intended outcomes of Pillar 3, the following partners have primary responsibility for achieving the quality use of medicines and medicines safety.

Partners and their broad responsibilities and functions to advance Pillar 3

Intended outcomes	Partner	Broad responsibilities and functions
<p>Individuals, their families and/or carers are empowered to actively participate in shared decision-making in relation to the quality and safe use of medicines and medicines-related services in the prevention, management and treatment of a specific health condition or indication and for the maintenance of good health.</p> <p>Adopting a person-centred approach, health professionals commit to, are trained and proactively supported to implement programs and initiatives to achieve the safe and quality use of medicines.</p>	Individuals, their families and/or carers	<p>Engage actively with the safe and quality use of medicines as part of a suite of treatment options.</p> <p>With support from relevant partners, build the knowledge and understanding of medicines, including the benefits and risks for the effective, safe and quality use of medicines. This includes considering the use of digital enablers where appropriate.</p>
	Consumer organisations and representatives, patient advocates, not-for-profits	Promote and build health, digital and medicines literacy among the Australian community, to help people participate in shared decision-making about medicines. This includes increasing the ability of people to find

Intended outcomes	Partner	Broad responsibilities and functions
		and understand evidence-based medicines-related information about the risks and benefits of medicines, and ensuring this information is accessible and appropriate to the needs of the individual.
	Health professionals	<p>Adopt and implement programs and initiatives to achieve the safe and quality use of medicines into clinical practice, including identifying the up-to-date list of medicines with the individual, their families and/or carers at every stage of care including at transition of care. This may include the best possible medication history and a commitment to reduce inappropriate polypharmacy.</p> <p>Ensure the safe collection and appropriate disposal of expired or unwanted medicines. Promote public awareness around issues associated with medicines including safe and secure disposal which minimises impact on the environment.</p> <p>Communicate the risks and benefits of medicines to enable consumers to make informed decisions about their medicines and build their health and medicines literacy.</p> <p>Ensure effective and respectful communication of information to support the safe and quality use of medicines.</p> <p>Ensure informed consent before sharing any health-related information.</p> <p>Maintain compliance with up-to-date best practice guidance on the prescribing, dispensing, supply, administration and deprescribing of medicines.</p> <p>Optimise the use of digital technologies in clinical practice to support the quality use of medicines and medicines safety.</p>
	Health professional organisations	Support health professionals in adopting and implementing the systems, programs and initiatives to achieve the safe and quality use of medicines.
	Commonwealth government and national agencies State and territory governments and agencies	<p>Coordinate and fund appropriate, medically informed programs, processes, structures and clinical environments to achieve the safe and quality use of medicines including raising awareness among the public and health professionals.</p> <p>Provide leadership and overall strategic direction on quality improvements relating to the safe and quality use of medicines</p>
	Researchers and academics	Research, trial, evaluate and report on outcomes, including in collaboration with other partners, to support the safe and quality use of medicines.

Intended outcomes	Partner	Broad responsibilities and functions
	Medicines industry, including software providers	<p>Promote the safe and quality use of medicines across all stages including research, evaluation, development, manufacture and supply.</p> <p>Ensure evidence-based, up-to-date, accurate, consistent, standardised, balanced, and easy to understand medicines-related information is available for health professionals and individuals, their families and/or carers.</p>
	Health educators, including higher education and professional training bodies	<p>Ensure that educational curricula, including undergraduate, postgraduate and continuing professional development programs, promote the quality use of medicines and medicines safety through a person-centred approach and shared decision-making.</p>
	Media	<p>Responsibly report on medicines and issues associated with their use.</p> <p>Monitor and manage digital platforms to protect individuals against harm from online disinformation and misinformation on medicines and medicines-related services.</p>

Pillar 4 - Collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs

To achieve the intended outcome of Pillar 4, the following partners have primary responsibility for promoting responsive, innovative and sustainable medicines industry and research sectors.

Partners, and their broad responsibilities and functions to advance Pillar 4

Intended outcomes	Partner	Broad responsibilities and functions
<p>Thriving, dynamic medicines industry and research sectors that are proactively supported to contribute to meeting current and future health needs in Australia and internationally. The sectors work within a positive, sustainable and responsive policy environment that delivers and promotes world-class innovation, including encouraging the development and commercialisation of medicines, new technologies and related services.</p> <p>A diverse medical research sector that generates high-quality evidence, strategies, systems and processes, which support ongoing improvements in the quality use of medicines and medicines safety.</p> <p>Collaborative, robust, efficient and reliable supply chains and networks that deliver equitable, timely, affordable and safe access to medicines and medicines-related services throughout Australia.</p>	<p>Medicines industry, including software providers and innovation hubs</p>	<p>Research, develop, commercialise, manufacture and supply medicines according to international best practice processes and procedures, to ensure that medicines meet appropriate quality, safety and efficacy standards.</p> <p>Engage in collaboration with all partners to ensure that the processes for medicines discovery, development, evaluation and access are safe, timely, efficient, transparent and they meet the health needs of all Australians.</p> <p>Ensure a reliable supply and distribution network of medicines for all Australians, irrespective of needs or location.</p>

Intended outcomes	Partner	Broad responsibilities and functions
	Researchers and academics	<p>Research and develop medicines according to international best practice processes and procedures which ensure that medicines meet appropriate quality, safety and efficacy standards.</p> <p>In collaboration with individuals, their families and/or carers, research and generate evidence to ensure the quality use of medicines and medicines safety.</p>
	<p>Commonwealth government and national agencies</p> <p>State and territory governments and agencies</p>	<p>Create a positive, aligned and stable policy and funding environment that encourages the growth of research on medicines and medicines-related services.</p> <p>Ensure a positive, aligned and stable policy, funding and regulatory environment that encourages the growth of industry for the manufacture, distribution and supply of high-quality medicines domestically and globally.</p> <p>Provide consistent and responsive frameworks for medicines and medicines-related services, and their distribution.</p> <p>Facilitate an expanding clinical trials environment, through harmonised, consistent and supportive policies, that encourages participation by individuals, their families and/or carers.</p>
	<p>Health professionals and health professional organisations</p> <p>Consumer organisations and representatives</p>	<p>Work collaboratively, constructively and transparently with governments, industry, researchers and individuals, their families and/or carers in the co-design, development, implementation and evaluation of medicines and medicines-related services.</p>
	Health educators, including higher education and professional training bodies	<p>Develop and deliver training programs to facilitate a capable and trained workforce to achieve the intended outcomes of this pillar.</p>
	Media	<p>Responsibly and accurately inform the public about new medicines, technologies and related services.</p> <p>Monitor and manage digital platforms to protect individuals against harm from online disinformation and misinformation on medicines and medicines-related services.</p>

Governance

The NMP is intended to guide and focus the efforts of all partners to encourage greater dialogue, collaboration and cooperation in achieving the vision and aim of the Policy. It is intended to be a living document, which is regularly reviewed and updated every five years or when material changes are necessary. The Commonwealth may initiate amendments to the NMP at any time and consult on proposed amendments.

The Commonwealth's role is to lead and encourage collaboration between partners toward shared goals, and promote transparency in relation to accountability, reporting and communication. This includes facilitating collaborative action on problems that cannot be solved by any one partner.

Flexible, responsive mechanisms that support effective, collaborative action and timely application of the efforts and expertise of relevant partners in setting shared priorities are vital to the NMP's success. Leadership is required at national, state and territory, partner organisations and individual program levels to monitor and report on achievements against the central pillars, how the NMP's principles have been put into action, and the overall impact of the NMP.

Existing governance structures may be used where appropriate and efficient, such as the Health Ministers' Meeting and Health Chief Executives Forum (or equivalents), which have oversight of national health priorities including the quality use of medicines and medicines safety.

Other governance structures, including specific committees and working groups, may be established or have terms of reference amended to support 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 diverse representation of consumer organisations, individuals, their families and/or carers at all levels of governance.

Implementation

Australia's NMP functions as a coordinating framework that sets out a vision and common aim, central pillars and intended outcomes for all partners to work towards. As no single partner can be completely responsible for achieving the NMP's aim, its implementation is a collective responsibility appropriately defined and documented at the program level by each partner.

The Commonwealth's role is to lead, facilitate, coordinate and monitor the identification, engagement and commitment of partners in achieving the NMP's aim, within agreed and transparent reporting structures where appropriate. The Commonwealth is accountable for ensuring policy alignment with key areas of national health, social and economic reform and driving action across Ministerial portfolios and levels of government.

Each partner should link and communicate their actions connected to the central pillars and the implementation of the NMP's principles, to support the collective understanding of what is being done to achieve the Policy's aim and the intended outcomes. The development of policies, strategies, services, programs and initiatives involving medicines and medicines-related services is to include a requirement to identify whether they are consistent with the pillars and principles of the NMP.

For the Commonwealth, implementation actions include:

- considering appropriate mechanisms and processes to ensure the participation of all partners, including diverse consumer partners, and to enhance transparency and accountability in overseeing the implementation, evaluation and communication of the NMP.
- working with the states and territories to pursue consistency across jurisdictions on issues relating to medicines and medicines-related services, including ensuring interoperability of systems, policies and procedures and clinical trial governance.

- collaborating with the states and territories to continue investment in programs and initiatives to achieve the safe and quality use of medicines for individuals, their families and/or carers, and training programs for health professionals to deliver these programs and initiatives.
- ensuring appropriate horizon scanning mechanisms are in place to identify and act proactively on the opportunity of future scientific and technological innovation.

For each partner accountable and responsible for processes and systems that support the delivery of the NMP, implementation actions should include:

- reviewing, documenting and monitoring their related policies, strategies, programs, initiatives and outcome measures to ensure consistency with the NMP's aim, principles, central pillars, and intended outcomes. This includes identifying and addressing any gaps or areas of misalignment with the NMP.
- investing in training and education programs to deliver culturally safe person-centred care and shared decision-making, particularly for vulnerable population groups.
- investing in co-design and developing specific programs and initiatives with input from individuals, their families and carers. This includes promoting and building health, digital and medicines literacy, with a focus on culturally safe medicines-related information, to help people participate in shared decision-making.

Evaluation

Australia's NMP describes the intended outcomes that partners must collectively strive to achieve. The monitoring and evaluation of the collective progress towards the intended outcomes can demonstrate the impact of the NMP and allow for the identification of emerging priorities.

Consistent with the NMP's principle of accountability and transparency, each partner is obliged to make publicly available the results of monitoring and evaluation associated with their NMP aligned programs and initiatives. This information must be accessible and understood to ensure there is shared understanding of NMP partners. The sharing of information and learnings supports a collaborative and respectful approach to progressing the NMP.

All partners responsible for policies, strategies, programs and initiatives aligned with the NMP should regularly evaluate each element to ensure they are contributing optimally to the aim of the NMP. The Commonwealth is also responsible for developing and maintaining a set of national indicators to measure progress against the intended outcomes of the NMP's pillars.

Figure 3 provides guidance on evaluation for partners to use when reporting their progress in achieving the intended outcomes of the NMP's pillars.

Figure 3 – Guidance for an evaluation strategy aligned to the NMP

<p>What questions will be asked?</p>	<ul style="list-style-type: none"> • How have the NMP’s principles been addressed in the development and implementation of related policies, strategies, programs and initiatives? • Has this contributed towards achievement of the intended outcomes of the NMP’s pillars?
<p>What will be evaluated?</p>	<p>Policies, strategies, programs and initiatives</p>
<p>How will progress be measured?</p>	<p>Indicators - National and program-level criteria</p>
<p>Who will be responsible for measuring and reporting?</p>	<p>All partners delivering actions aligned to the NMP’s pillars</p>
<p>How will the results be communicated?</p>	<p>Annual reports, summaries, conferences and ministerial/government statements</p>

Concluding statements

The vision of the NMP can be achieved by a collective and collaborative approach by all partners towards improving the health, social and economic outcomes for all Australians. Fundamental to the success of this Policy is engaging the Australian public in achieving the vision and aim of the NMP. To assist with this, a plain language version of the NMP is available to ensure it is accessible and easily understood by all Australians.