Australian Government
Department of Health

Draft National Medicines Policy
COMMITTEE'S DRAFT

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 Policy relates to medicines research and development, regulation, manufacture, evaluation, supply 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 aim of the Policy by placing the individual at the centre, and by focusing on and responding to the needs of Australia's diverse population.

The success of this Policy 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 legislation, policies, strategies, programs and initiatives across the health system. Achieving the Policy's aim will require close alignment with key areas of health reform in Australia and action through a whole-of-government approach.

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

Vision

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

This vision will be realised through the creation of an environment with effective partnerships, structures and processes with defined responsibilities to support the NMP.

Aim

The aim of the NMP is to ensure:

- Equitable, timely and affordable access to high-quality and safe medicines and medicines-related services for all Australians.
- Medicines are used optimally with a focus on person-centred care.
- Support for a positive and sustainable environment to drive innovation and research, including translational research, and the development of medicines and medicines-related services.

Scope

The term 'medicine' covers a broad range of products that are used to prevent, treat, monitor 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 products, complementary medicines, and traditional medicines, including Aboriginal and Torres Strait Islander traditional medicines. Devices used to administer and monitor the response to medicines are also included.

The term 'medicines-related services' include services and programs that support the quality use of medicines and medicines safety. Examples include medication review services and diagnostic services, including for personalised medicines.

This broad definition means the NMP can adapt and respond to new and emerging treatments and technologies, or new or improved medicines-related services.

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, 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 will be engaged in a collaborative and cooperative manner to achieve the best health, social and economic outcomes for all Australians. Each partner has a role in progressing the Policy through demonstrating respect for and recognition of the expertise and contribution of other partners (Figure 1).

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

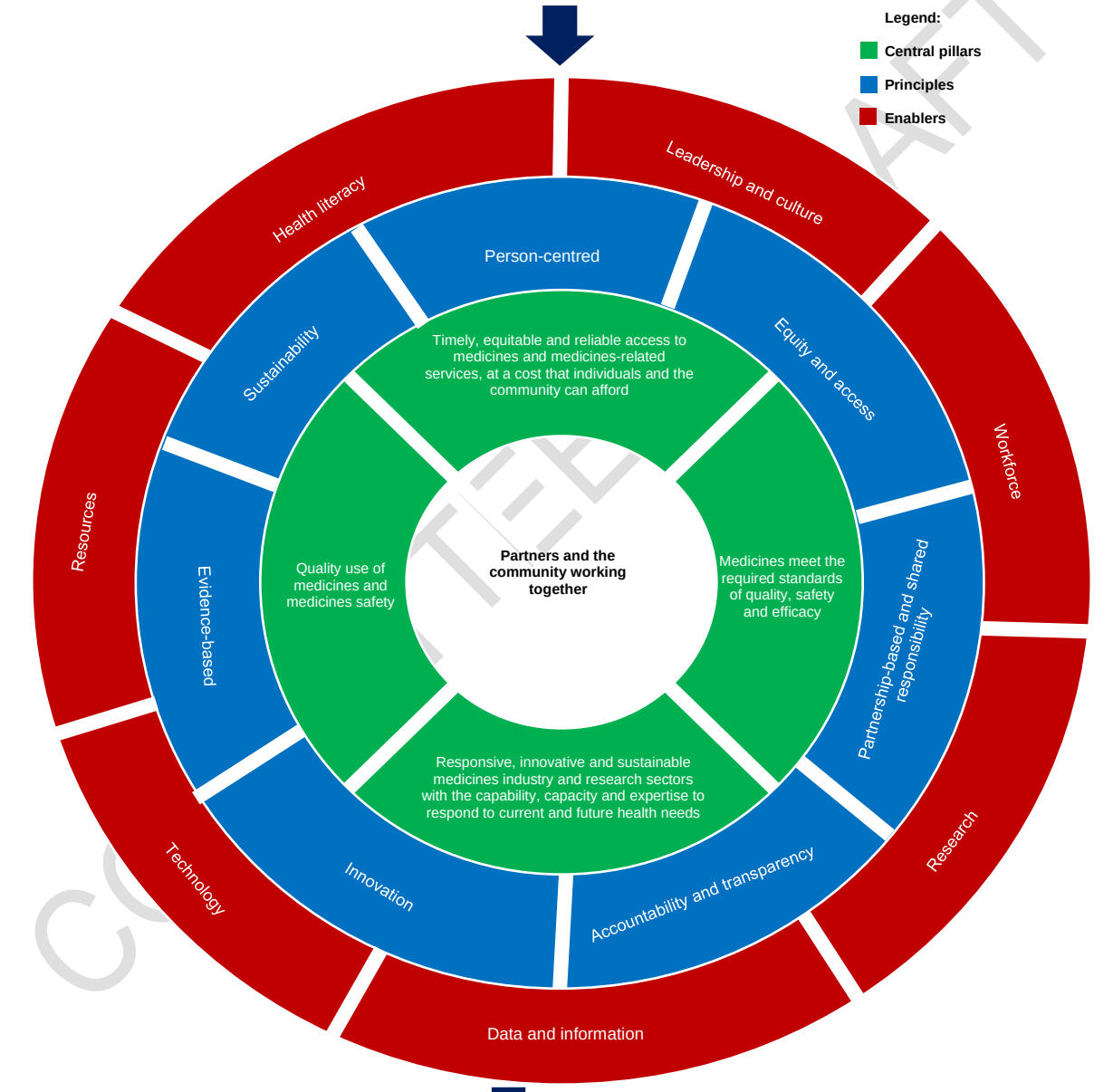
Central pillars, principles and enablers

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

Aim
To ensure:
- Equitable, timely and affordable access to high-quality and safe medicines and medicines-related services for all Australians.
- Medicines are used optimally with a focus on person-centred care.
- Support for a positive and sustainable environment to drive innovation and research, including translational research; and the development of medicines and medicines-related services.



Making partnerships work

Co-design, development and implementation of the related policies, strategies, programs, and initiatives to meet the aim of the NMP and the outcomes of the NMP pillars

Evaluation of the related policies, strategies, programs, and initiatives to meet the aim of the NMP and the outcomes of the NMP pillars

Central Pillars

The central pillars of the NMP are:

- Timely, equitable 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.
- Responsive, 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 will be supported and enabled to be informed and active participants in all decision-making, acknowledging their aspirations, diversity and lived experience. This includes developing and building health literacy, so that individuals, carers and families, and the broader community are informed and active participants in decision-making. Consumers will be supported to be involved at all levels of the NMP, including in the co-design and development, implementation and evaluation of its related policies, strategies, programs and initiatives.
Equity and access	All actions relating to the NMP will focus on delivering and achieving positive health outcomes that matter most to people and their communities. All Australians will have access to safe, effective and high-quality medicines, culturally appropriate medicines-related services and culturally appropriate medicines information. Access will be 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 priority groups within the community. These groups include Aboriginal and Torres Strait Islander people; people from culturally and linguistically diverse backgrounds; children and older people; people with disability; people living in rural and remote areas; people of low socioeconomic status; people living with rare and under-recognised diseases; people with mental illness; lesbian, gay, bisexual, transgender, queer or questioning, intersex and/or other sexuality and gender diverse people (LGBTQI+); and other priority groups. People may identify as belonging to one or more of these priority population groups, and as such, may have compounding health and wellbeing experiences that must be considered.
Partnership-based and shared responsibility	Active, respectful dialogue, collaboration and cooperation will be established and maintained between partners - listening to and recognising the wisdom and expertise of each partner. All partners will act responsibly, as stewards of the NMP.
Accountability and transparency	All partners will accept responsibility for their actions and will be held accountable for advancing the progress of the NMP's central pillars. All activities will be undertaken, and information shared, in a respectful and transparent way.

Innovation	All partners will proactively support new and improved ways to respond to current and future health needs and deliver greater value to achieve the best health, social and economic outcomes. This includes reducing inequities across society and improving the health system, with a particular focus on medicines and medicines-related services.
Evidence-based	All partners will apply relevant, current and context specific evidence to guide decision-making, program design and communication. This will include information on safety, efficacy and effectiveness, and consideration of both real-world experience and patient reported experience and outcomes.
Sustainability	All partners will consider the health, social and economic impact and sustainability of the strategies, policies, programs or initiatives they deliver. All partners will work to reduce the impact on the natural environment from the research, development, manufacture and supply of medicines. This includes the safe collection and appropriate disposal of expired or unwanted medicines, devices and medicines packaging.

Enablers

The NMP consists of seven enablers that are critical to the success of the NMP. These include:

- **Health literacy –** to build the skills, knowledge, understanding, motivation, capacity and confidence of a person to access, understand and use information to make decisions about their health and health care. The whole health system will respond to an individual's health literacy needs, by delivering person-centred health information, education, support and services. The way information is developed will be appropriate to each person's culture and language, health beliefs, accessibility, disability and information needs. Digital tools and technologies will be used to help 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 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, respectful, flexible, adaptable and transparent manner. A culture that is open to creativity, learning and quality improvement will be developed, supported and promoted by all partners.
- **Workforce –** to ensure an adequate workforce that is knowledgeable, competent, accessible and resourced to provide coordinated, integrated and person-centred care. Health professionals will 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 –** to deepen knowledge and facilitate innovation and delivery of new and better medicines and new and improved medicines-related services to reduce harm and inform continuous improvement in the quality use of medicines and medicine safety.
- **Data and information –** to ensure the responsible collection, secure storage, appropriate use and management of data and information. Data driven insights and digital integration will enable evidence-based decisions to improve health outcomes, the quality use of medicines, medicines safety and health system efficiency. This will include the capability of horizon scanning to use and translate data in predicting future trends in diseases and emerging disruptive and innovative therapies and technologies.
- **Technology –** to embrace and adopt digital information and technologies, and methods that are validated and interoperable to drive improvements in access, quality, safety and efficiencies for all Australians across their health journey and use of medicines.
- **Resources –** to ensure appropriate and adequate resources are distributed, and effectively and efficiently used, to achieve the aim of the NMP.

Pillar 1: Timely, equitable 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 and timely 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, affordability and the health, social and economic benefits. National programs that provide subsidised access to medicines include 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 may be privately purchased. There may be a need for specific access arrangements between federal, state and territory governments for certain technologies.

Timeliness

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

Timeliness has several other contexts and barriers for consumers, including not being able to access medicines and medicines-related services due to shortages or supply challenges, particularly for those in rural and remote communities. This requires an open and transparent commitment by all partners to work together to minimise the impact of shortages and supply challenges of essential medicines.

Equity

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

This pillar focuses on eliminating health inequities that may be experienced by priority groups, as outlined in the principle of ‘Equity and access’. Specific examples of issues experienced by priority populations which need to be considered and addressed by partners include:

- Aboriginal and Torres Strait Islander leadership and self-determination is needed in all partnerships to enable shared decision-making in identifying priorities and to drive solutions given the substantial barriers Aboriginal and Torres Strait Islander people experience.

- People from culturally and linguistically diverse backgrounds are included in partnerships to co-design solutions to increase access to medicines, culturally appropriate medicines information and medicines-related services.
- People living with disability may face specific challenges including accessing the required medicines formulations and medicine reviews, communicating with health professionals, and accessing easy to read written information about their medicines.
- People from rural and remote communities face specific and ongoing barriers associated with the cost, supply and distance to access medicines and health services.
- People, including children, living with rare and under-recognised diseases often face inequities due to the scientific and technical complexities of data and its collection, and the absence of evidence for the evaluation and subsidisation of treatments for rare conditions.

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

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, or families experiencing high health care costs.

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

Initial and continued investment decisions should be informed by rigorous health technology evaluation, including the consideration of incorporating real-world evidence and patient reported outcomes, where appropriate.

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 quality and safe use of medicines.**

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

Protecting the health and safety of the community

Ensuring the quality, efficacy and safe use of medicines is important across the medicines lifecycle and patient journey. Ongoing quality assurance processes guarantee that medicines continue to meet the highest standards of quality, safety and efficacy for specified conditions or indications.

These processes include assessments both before and after a medicine goes on the market. Generally, the outcomes of these assessments will be available to the public. This promotes transparency and shows how quality, safety and efficacy standards have been achieved and maintained.

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

- improve access to up-to-date, easily understood, evidence-based information to help people make informed health care decisions.
- build the public's knowledge about medicines regulation, such as reporting adverse events, to support the quality use of medicines.
- assist in identifying and reporting potential problems with medicines use, 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 supportive of timely access to innovative medicines and medicines-related services.

This can be achieved through the:

- adoption of a risk/benefit-based approach to regulation.
- use of rational and transparent criteria and processes to evaluate and manage a nationally and internationally standardised approach to medicines regulation.
- pursuit of opportunities to collaborate with recognised international regulatory agencies to reduce duplication and facilitate earlier access to medicines for all Australians.
- regulations that ensure appropriate practices are followed in the research, development, production, supply and advertising of medicines.

- clear and transparent processes for responding to regulatory problems or breaches quickly and proportionately, including communicating the outcomes to all partners and affected individuals.
- availability of evidence-based, accurate and easily understood medicines information for all consumers.
- development and implementation of flexible and adaptable processes, where appropriate, to respond to high unmet clinical need, public health emergencies and natural disasters.
- development of a positive and cooperative relationship between regulators and the medicines industry and research sector, using effective models for co-regulation, where appropriate.

Pillar 3: Quality use of medicines and medicines safety

Intended outcomes:

- **Individuals, families and 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 ill health.**
- **Adopting a person-centred approach, health professionals commit to, are trained and proactively supported to implement programs and initiatives to achieve the quality use of medicines and medicines safety.**

The quality use of medicines and medicines safety is a National Health Priority Area.

The quality use of medicines includes:

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

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

Person-centred care, including shared decision-making, is essential for the quality use of medicines. Health literacy helps people to decide, with their health practitioner, whether to use a medicine. Health literacy means people know how to find and use information that is relevant, accurate and meaningful to them. The NMP partners recognise that this relies on a collaborative effort to:

- provide culturally appropriate, person-centred services, including health and medicines information and support for both face to face and online interactions.
- develop the skills and confidence of people to manage their own health and medicines, including when and where to get help, when needed.
- encourage people to be active, empowered and informed participants in their health care.
- encourage people to ask for, and use objective, evidence-based information, resources, and services as part of a shared approach to informed decision-making.
- 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 are less well equipped to prevent and manage sickness. The quality use of medicines must therefore involve consumers including those from priority groups in the co-design, implementation and evaluation of health and medicines-related services.

All NMP partners recognise that focusing on health literacy is not limited to supporting the quality use of medicines. It contributes to positive outcomes for a person's engagement with the health system throughout their lifetime.

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. 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 the context of following best practice. Health professionals will be trained in person-centred care and informed decision-making to enable discussions on medical and non-medical treatment options.

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

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

NMP partners 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 of programs and initiatives supporting the quality use of medicines and medicine safety.
- policies, guidelines, accreditation standards and clinical information systems that guide the quality use of medicines and medicine safety. 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 objective, credible, evidence-based and current information relevant to the Australian health system, that spans the full life cycle of medicines and patient journey, 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: Responsive, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs

Intended outcomes:

- **Dynamic industry and medical research sectors which are proactively supported for their contribution in meeting current and future health needs in Australia and internationally. The sectors work within a supported, sustainable and responsive environment that delivers and promotes innovation and encourages the development and commercialisation of new medicines and related technologies.**
- **A diverse research sector which is supported to generate high-quality evidence, strategies, systems and processes which improve the quality use of medicines and medicines safety.**
- **A robust, responsive and reliable supply chain network that provides the timely and equitable distribution of medicines throughout Australia.**

The medicines industry and research sectors significantly contribute to achieving better health outcomes and growing positive social and economic development in Australia. Responsive, dynamic and sustainable medicines industry and research sectors are critical to ensure that all Australians can benefit from their innovations. The NMP commits all partners to a coordinated and aligned approach between health, research, education and industry policy.

A supportive and responsive industry and medicines research environment

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

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

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

With the aim of building a reliable and integrated supply chain, 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 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 by utilising agreed and transparent evaluation and reporting mechanisms. This will require 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 will 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 will 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, will work together collaboratively, cooperatively and be respectful of the expertise of each other.

Pillar 1 - Timely, equitable 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 will 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 and timely manner, leading to the achievement of the best health, social and economic benefits for all Australians.	Consumer organisations, including not-for-profits, and peak bodies	Support and advocate for consumer engagement and 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.
	Health practitioners	Discuss options and appropriately recommend, prescribe or supply medicines and medicines-related services, applying a person-centred approach, to promote the quality use of medicines and medicines safety.

	Commonwealth Government	Deliver national health programs that ensure equitable, timely, affordable and reliable access to medicines and medicines-related services. Be accountable for proactive engagement and alignment across partner jurisdictions, ensuring the interoperability of systems, policies and procedures. Support nationally consistent platforms, governance, processes and guidelines for a safe, accessible, active and progressive clinical trial sector.
	State and territory governments	Deliver reliable access to equitable and affordable medicines through publicly funded services. Be accountable for proactive engagement and alignment across partner jurisdictions, ensuring interoperability of systems, policies and procedures and clinical trial governance.
	Industry	Research, develop and supply medicines which provide the best health and socioeconomic value to the individual and the community, in a timely and sustainable way.
	Researchers	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.
	Health professional organisations and other health related agencies	Develop and support systems, processes and guidelines, which promote the safe, timely, equitable and reliable access to medicines.
	Media	Report responsibly on issues relating to the safe, timely, equitable, reliable and affordable access to medicines.

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

To achieve the intended outcomes of pillar 2, the following partners will 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
Australia's medicines regulatory processes are efficient, protect health and safety and are trusted by the community. **Medicines are safe and effective, and**	Consumer organisations, including not-for-profits, and peak bodies, individuals, carers, and families	Promote and facilitate consumer involvement into the approval of medicines and the monitoring of adverse events or product quality issues. Facilitate consumer involvement into the design of a coordinated and responsive medicines adverse events reporting system. Engage and promote an understanding of the medicines regulatory system and facilitate consumer involvement into evidence-based medicines information to support the safe, effective and quality use of medicines.

their labelling and supporting information is readily available and supports the quality and safe use of medicines.	Health practitioners	Prescribe, supply or administer medicines in line with relevant guidelines, and in consultation with the person taking the medicine, or their carers and families. Commit to a nationally coordinated pharmacovigilance program including monitoring and reporting adverse events and medicines safety issues in clinical practice.
	All governments and regulatory agencies	Work collaboratively and consistently to achieve best practice, responsive and relevant regulation for the research, development, production, supply and advertising of medicines. Ensure international relevance and alignment, where appropriate. Ensure best practice communication in medicines information, including labelling, Product Information (PI) and Consumer Medicines Information (CMI).
	Industry and researchers	Adhere to relevant research and development, manufacturing and regulatory standards, including post-marketing safety monitoring and reporting. Ensure appropriate language in the development and review of easy to understand medicines information for consumers.
	Professional organisations	Promote best practice in reporting adverse events or other medicines related issues to appropriate authorities.
	Media	Responsibly and accurately inform the public about product safety and quality issues.
	Health educators	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.

Pillar 3 - Quality use of medicines and medicines safety

To achieve the intended outcomes of pillar 3, the following partners will 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
Individuals, families and 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 ill health.	Individuals, carers, and families	With support from relevant partners, build the knowledge and understanding of medicines, including the benefits and risks for the safe and appropriate use of medicines. This includes considering the use of digital enablers where appropriate.
	Consumer organisations, including not-for-profits, and peak bodies	Promote and build health literacy among the Australian community, to help people participate in shared decision-making about medicines. This includes increasing the ability of people to find and understand evidence-based information about the risks and benefits of medicines, and ensuring this information is

Adopting a person-centred approach, health professionals commit to, are trained and proactively supported to implement programs and initiatives to achieve the quality use of medicines and medicines safety.		accessible and appropriate to the needs of the individual.
	Health practitioners	Adopt and implement programs and initiatives to achieve the quality use of medicines and medicines safety into clinical practice. Ensure the safe collection and appropriate disposal of expired or unwanted medicines. Promote public awareness around issues associated with medicines including safe disposal. Communicate the risks and benefits of medicines to enable consumers to make informed decisions about their medicines and build their health literacy. Ensure effective and respectful communication of information to support the quality use of medicines and medicines safety. Ensure informed consent before sharing any health information. Maintain compliance with up-to-date best practice guidance on the prescribing, supply, administration and deprescribing of medicines. Optimise the use of digital technologies in clinical practice to support the quality use of medicines and medicines safety.
	Health professional organisations	Support health practitioners in adopting and implementing the systems, programs and initiatives to achieve the quality use of medicines and medicines safety.
	Commonwealth, state and territory governments	Coordinate and fund programs and processes to achieve the quality use of medicines and medicines safety including raising awareness among the public and health professionals.
	Industry	Promote the quality use of medicines across all stages including research, development, manufacture and supply. Ensure evidence-based, up to date, balanced and easy to understand information is available for health professionals and consumers.
	Health educators, including higher education and professional training bodies	Ensure that educational curricula, including undergraduate, postgraduate and continuing professional development programs, promotes the quality use of medicines and medicines safety through a person-centred approach and shared decision making.
	Media	Responsibly report on medicines and issues associated with their use. Monitor and manage digital platforms to protect individuals against harm from online disinformation and misinformation on medicines and medicines-related services.

Pillar 4 - Responsive, 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 will 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
Dynamic industry and medical research sectors which are proactively supported for their contribution in meeting current and future health needs in Australia and internationally. The sectors work within a supported, sustainable and responsive environment that delivers and promotes innovation and encourages the development and commercialisation of new medicines and related technologies. **A diverse research sector which is supported to generate high-quality evidence, strategies, systems and processes which improve the quality use of medicines and medicines safety.** **A robust, responsive and reliable supply chain network that provides the timely and equitable distribution of medicines throughout Australia.**	Industry	Research, develop, commercialise, manufacture and supply medicines according to international best practice processes and procedures which ensure that medicines meet appropriate quality, safety and efficacy standards. Engage in collaboration with all partners to ensure that the processes for medicines discovery, development, evaluation and access are timely, efficient, transparent and they meet the health needs of all Australians. Ensure a reliable supply and distribution network of medicines for all Australians, irrespective of needs or location.
	Researchers	Research and develop medicines according to international best practice processes and procedures which ensure that medicines meet appropriate quality, safety and efficacy standards. In collaboration with consumers, research and generate evidence to ensure the quality use of medicines and medicines safety.
	Commonwealth, state and territory governments	Create a positive and stable policy and funding environment that encourages the growth of research on medicines and medicines-related services. Ensure a positive 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. Provide consistent and responsive frameworks for medicines and medicines-related services, and their distribution. Facilitate an expanding clinical trials environment through unified, consistent and supportive policies that encourages patient participation.
	Health practitioners, health professional organisations, consumer organisations	Work constructively and transparently with governments, industry, researchers and consumers in the co-design and development implementation and evaluation of medicines and medicines-related services.
	Health educators, including higher education and	Develop and deliver training programs to facilitate a capable and trained workforce to achieve the intended outcomes of this pillar.

	professional training bodies	

Governance framework

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

Governance structures, including specific committees and working groups, may be established 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 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. Leadership is required 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.

Implementation

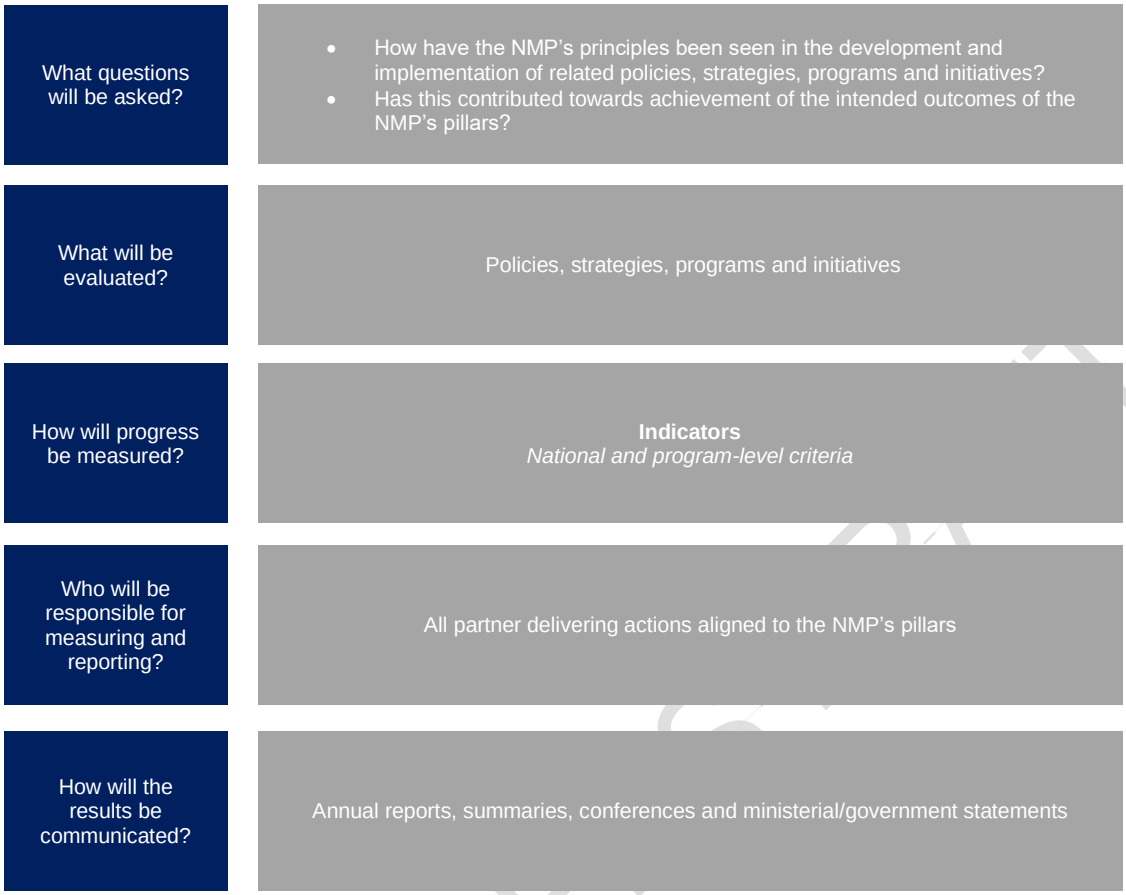
Australia's NMP functions as a coordinating framework that sets out the central pillars and intended outcomes for all partners to work towards. As no single partner can be completely responsible for achieving the Policy's aim, its implementation is a collective responsibility appropriately defined and 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 in achieving the NMP's aim, within agreed and transparent reporting structures.

Each partner should communicate the linkages between their actions, connection 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, services, programs and initiatives involving medicines will include a requirement to identify whether they are consistent with the pillars and principles of the NMP.

Evaluation

Australia's NMP describes the intended outcomes that partners will collectively strive to achieve. The monitoring and evaluation of the collective progress towards the intended outcomes will demonstrate the impact of the NMP and allow for the 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 associated with their NMP aligned programs and initiatives. This information will be accessible and understood to ensure there is shared understanding of NMP partners This sharing of information and learnings will support a collaborative and respectful approach to progressing the NMP. Figure 3 represents guidance on evaluation for partners to use when reporting their progress in achieving the outcomes of the NMP's pillars.

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



Concluding statements

The vision of the NMP will 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 will be engagement of consumers in achieving the vision and aim of the NMP.