



# Review of the National Medicines Policy

## Discussion Paper

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## Acronyms

ACSQHC	Australian Commission on Safety and Quality in Health Care
AHPF	Australian Health Performance Framework
APAC	Australian Pharmaceutical Advisory Council
ARTG	Australian Register of Therapeutic Goods
ATAGI	Australian Technical Advisory Group on Immunisation
CAR T	Chimeric Antigen Receptor therapy
DUSC	Drug Utilisation Sub-Committee
HoR	House of Representatives
HTA	Health Technology Assessment
MAP	Managed Access Program
MRFF	Medical Research Future Fund
MSAC	Medical Services Advisory Committee
NatRUM	National Return of Unwanted Medicines
NHRA	National Health Reform Agreement
NIP	National Immunisation Program
NMP	National Medicines Policy
NPS	National Prescribing Service
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PhARM	Pharmaceutical Health and Rational use of Medicines (Working Group)
PHN	Primary Health Network
PMR	Post Market Reviews
PRA	Pharmaceutical Reform Agreement
PREM	Patient Reported Experience Measure
PROM	Patient Reported Outcome Measure
QUM	Quality Use of Medicines
TGA	Therapeutic Goods Administration
WHO	World Health Organization

# 1. Background and Context

## Australia's National Medicines Policy (NMP)

Published in 2000, the current NMP aims to deliver positive health outcomes for all Australians through their access to and appropriate use of medicines. The NMP is a well-established and universally endorsed framework based on partnerships between consumers and all segments of the medicines sector to promote the NMP's four central objectives.

These are:

- timely access to the medicines that Australians need, at a cost that individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry

The NMP is a high level document that concisely outlines these four objectives, and identifies the partners responsible for achieving these objectives. The policy also discusses the need for strong alignment and coordination to meet the challenges and overcome the complexity associated with achieving each of the objectives.

The objectives and the principles of the policy continue to resonate today. However, the medicines policy landscape has changed in the twenty years since its publication. Therapeutic and technological innovations are expanding treatment options and improving health outcomes. Patients' expectations have grown, and increased knowledge and insight have driven the immediacy of access to the latest technologies. Patient voices are also better organised through social media and disease specific groups. Australians are living longer, often with multiple chronic conditions and healthcare delivery is being transformed by digital advances.

It is therefore appropriate that the NMP is reviewed to ensure that the changes in the health system environment are addressed, and where applicable, the policy updated to take account of these changes.

# 2. Consultation Overview

## Why are we consulting?

The primary purpose of this consultation process is to provide the Review Committee with an appreciation of the breadth of stakeholders' views, to support a refresh of the NMP. The Review's Terms of Reference address areas that will support this refresh as a high-level policy framework, rather than reviewing the activities and programs aimed at delivering the policy.

Stakeholders are encouraged to provide their feedback towards supporting a refresh of the high-level framework. This will assist in future-proofing the policy, as adopting detailed program specific feedback within the policy risks dating the revised NMP and reducing its universality.

## Expert Advisory Committee

The Minister has established an Expert Advisory Committee (the Committee) to lead the Review of the NMP for the Department of Health. The Committee will report to the Minister for Health through the Chair.

The Committee is Chaired by the Deputy Chief Medical Officer and Principal Medical Advisor, Professor Michael Kidd AM. Its members include Professor Lloyd Sansom AO; Mrs Janette Donovan; Mr David Herd and Dr Sarah Dineen-Griffin. This Committee brings a wide range of

experience covering medicines policy, clinical practice, consumer engagement and industry insights to the Review.

## Terms of Reference

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

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

## Reporting

Following the close of the Discussion Paper consultation period, a draft revised NMP will be prepared. A stakeholder forum will also be organised in late November or early December 2021 to discuss the draft policy and assist with the refinement of the document.

The Review Committee also anticipates that some stakeholders will be engaging with the NMP Review because they have feedback related to a specific program. In acknowledgement of this engagement, the Review Committee will summarise key themes relating to this feedback in a report to the Minister.

## How to respond

The Committee welcomes all feedback to support the refresh of the NMP.

This Discussion Paper has been prepared to provide context for the Review, and to encourage consideration of the issues the Review could address. It has been developed with consideration of the published literature and stakeholder feedback from the NMP Review January 2020 Stakeholder Forum (referred to in this document as the Stakeholder Forum). A summary of the high-level themes emerging from this forum is available for download from the Consultation Hub.

The Discussion Paper poses questions at the end of each section to help guide your feedback. You may wish to respond to all or some of the questions. You are also welcomed to respond directly to the Review's Terms of Reference.

References to relevant strategies and initiatives are provided as examples to prompt discussion and the options canvassed are to stimulate ideas. This consultation paper should be read with reference to the [National Medicines Policy \(2000\)](#) (see supplementary document).

Please submit your views through the [Department of Health's Consultation Hub](#) – this will step you through the questions seeking specific feedback. Alternatively, the full Discussion Paper can be downloaded, and a response document can be uploaded on the final page.

The consultation will close on **Friday 8 October 2021**.

To contact the NMP Review Secretariat, please email: [NMP@health.gov.au](mailto:NMP@health.gov.au).

## Privacy Notification

The Australian Government Department of Health (Department) is bound by the *Privacy Act 1988* and the Australian Privacy Principles (APPs).

Your personal information is protected by law, including the *Privacy Act 1988* (Privacy Act) and the Australian Privacy Principles, and is being collected by the Department, via Citizen Space, for the purposes of conducting a consultation process in relation to the NMP Review.

The Department will collect your personal information at the time that you provide a submission, unless you choose to make a submission anonymously, and you are not reasonably identifiable from the information provided in your submission.

While the Department encourages respondents to self-identify in their submission, there is no requirement to do so. If you choose to make an anonymous submission, the Department will be unable to attribute views to you in the Report or follow-up with you on any issues raised.

If you consent, the Department may, at its discretion, publish part or all of the information provided in your submission in the Review's Stakeholder Consultation Report (Report). If information from your submission is published, the Department may identify you and/or your organisation as the author of the submission, if you consent to being identified. Please note that your email address will not be published, and responses may be moderated to remove content that is inappropriate/offensive or contains sensitive information.

If you wish your submission or part of your submission to be kept confidential, you must notify the Department. You should not include information in your submission about another individual who is identified or is reasonably identifiable. If you need to include information about another individual in your submission, you will need to inform that individual of the contents of this notice and obtain their consent to the Department collecting their personal information.

The Australian Government may, at its discretion, share the Report or its findings with interested parties. The Department may disclose your responses to sub-contractors. Commonwealth contractors will be bound by the *Privacy Act 1988*.

The Commonwealth Freedom of Information Act 1982 (FOI Act) gives individuals a legally enforceable right to request access to documents held by government departments. This includes documents provided in response to the consultation process in support of the NMP Review. The FOI Act is available here: <https://www.legislation.gov.au/Details/C2020C00366>.

The Department has an APP privacy policy which you can read at <https://www.health.gov.au/resources/publications/privacy-policy>. You can obtain a copy of the APP privacy policy by contacting the Department using the contact details set out at the end of this notice. The APP privacy policy contains information about:

- how you may access the personal information the Department holds about you and how you can seek correction of it;
- how you may complain about a breach of the APPs;
- a registered APP code that binds the Department; and
- how the Department will deal with complaints.

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### 3. Themes and questions relating to the Terms of Reference

**Terms of Reference 1: Evaluate the current NMP objectives and determine whether these should be modified or additional objectives included. This includes consideration of the proposed Principles to be included within the NMP.**

The goal of Australia's NMP is to "optimise health outcomes for all Australians through a collaborative partnership with key stakeholders, focusing especially on people's access to, and wise use of, medicines".

In support of achieving this goal, four central objectives are outlined in the NMP and described in further detail below. While these objectives outline the high-level approach to achieving this goal, the principles that underpin these core objectives are not detailed in the NMP. Principles provide an explicit, high-level direction for the planning, design and implementation of programs and initiatives to achieve objectives. Feedback from the Stakeholder Forum suggested that consideration be given to future proofing the revised policy, which could be achieved through articulating the policy's overarching principles.

#### **Proposed Principles of the National Medicines Policy**

The following principles are proposed for inclusion in the refreshed NMP. It is expected that these principles should be evident in the planning, design and implementation of programs, systems and initiatives created to deliver positive health outcomes for all Australians through their access to, and appropriate use of, medicines.

The principles have been drawn from existing strategies and frameworks relating to the NMP (i.e. [National Strategy for QUM](#) and [Australia's Health Technology Assessment \(HTA\) Framework](#)), stakeholder feedback, and the current approaches to delivering on the NMP's core objectives.

Proposed Principles:

- **Equity** – all Australians receive effective, safe, high-quality, and affordable access to medicines when needed irrespective of background or personal circumstance.
- **Consumer centred approach** – consumers should be informed, engaged, and empowered to participate in medicines policy, recognising their key role in supporting the achievement of the policy's objectives.
- **Partnership based** – establish and maintain active, respectful, collaborative, and transparent partnerships, to harness stakeholders' skills, experience, and knowledge.
- **Accountability and transparency** – all stakeholders are identified and accountable for their responsibilities and actions towards delivering or contributing to the achievement of the policy's objectives, within a transparent framework.
- **Stewardship** – all stakeholders have a shared responsibility to ensure that the policy's objectives are met in an equitable, efficient, and sustainable manner, as stewards of the health system.

#### **Question:**

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

## **Objectives of the National Medicines Policy**

The NMP's four central objectives are outlined on [pages 2 to 4 of the current policy document](#). A brief overview of each of these objectives, including key policy implementation mechanisms are detailed below. While these objectives are distinct, the policy continually emphasises their interrelations.

### ***Access to medicines***

Ensuring timely access to medicines that Australians need, at a cost individuals and the community can afford, relies on rigorous and adaptable health technology assessment (HTA) processes. This allows for the rigorous assessment of new treatments and therapies as they emerge, while also evaluating the use of medicines in the community.

The Pharmaceutical Benefits Scheme (PBS) is the key mechanism through which this objective is achieved – providing Australians with reliable, timely and affordable access to a wide range of medicines. Australians also access medicines through their public hospitals and as part of clinical trials and access programs. The PBS provides affordable access to most medicines in Australia, including some of those used in the treatment of rare diseases. Fully subsidised access to specific essential medicines for rare and life-threatening medical conditions is also provided through the Life Saving Drugs Program (LSDP). The LSDP is separate to the PBS, and medicines on the LSDP are available to eligible patients at no cost and for as long as clinically necessary. There are currently sixteen medicines on the LSDP for the treatment of 10 conditions.

[The House of Representatives Standing Committee on Health, Aged Care and Sport Inquiry into approval processes for new drugs and novel medical technologies in Australia](#) (referred to as the HoR Inquiry within this document) is focusing on the programs and processes that support the delivery of this objective. The public submissions and hearing from this Inquiry are being considered by the Committee and where relevant, will inform the Committee's work. Recent changes led by the Therapeutic Goods Administration (TGA) in response to the [Review of Medicines and Medical Devices Regulation](#) and [recent improvements to PBS processes](#) will also be informative.

### ***Quality, safety, and efficacy of medicines***

The NMP commits all partners to consider that the quality, safety, and efficacy of medicines available in Australia, should be equal to that of comparable countries (i.e. economic/health systems/education). A list of requirements to support this are listed in the [policy](#).

The TGA is responsible for ensuring that therapeutic goods available for supply in Australia meet the required standards of safety, quality, and efficacy. Therapeutic goods must generally be entered on the Australian Register of Therapeutic Goods (ARTG) prior to import, export, supply, or advertising, unless an exemption applies.

### ***Quality use of medicines***

The quality use of medicines (QUM) is focused on reducing preventable harm and promoting the achievement of optimal health outcomes with reference to medicines use, by ensuring the right patient receives the right medicine at the right time. The NMP commits all partners to consider that all medicines be used judiciously, appropriately, safely, and efficaciously. The QUM is also supported by educational initiatives for consumers, carers and health professionals.

Medicines are one of the most common treatments used in health care, and there are growing numbers of people with multiple chronic conditions, prescribed multiple medicines. Medicines can also be used to prevent disease, with the term 'medicines' including prescription, over-the-counter and complementary medicines. This is associated with complexities relating to medicines usage and safety, highlighting the importance of promoting and monitoring the QUM.

Monitoring the utilisation of medicines is an essential management tool in facilitating the objectives of the NMP. The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) maintains a national focus in collecting, analysing, and interpreting data on the utilisation of medicines in Australia. The publications from DUSC aim to uphold the NMP in terms of assisting consumers and health professionals in understanding the costs, benefits, and risks of medicines.

The [post-market review program](#) monitors the use of medicines listed on the PBS. Post-market reviews (PMRs) provide a systematic approach to examine and address QUM concerns relating to medicines listed on the PBS. PMRs involve a review of a specific medicine or group of medicines in the current treatment context, including actual utilisation, comparative efficacy, treatment guidelines and health outcomes. These reviews contribute to QUM through establishing and promoting best-practice and appropriate use, addressing specific QUM issues, and ensuring that the price paid for the medicine reflects the health outcomes being achieved.

There are a range of partners that contribute towards the QUM. These include, but are not limited to, peak professional bodies, patient support groups, industry (through funding patient support programs and healthcare professional education), Primary Health Networks (PHNs), government agencies such as the Australian Commission on Safety and Quality in Health Care (ACSQHC), Aged Care Quality and Safety Commission and NPS MedicineWise. The Australian Government also directly funds key QUM programs and initiatives, such as community pharmacy programs and services, including medication management services, through the Seventh Community Pharmacy Agreement.

NPS MedicineWise has played a central role in implementing this objective in primary care through its delivery of multi-faceted, evidence-based educational programs to promote the QUM. In addition to educational programs, activities that minimise the misuse of medicines, such as the [National Return of Unwanted Medicines \(NatRUM\)](#) program also contribute towards achieving the QUM. This program ensures that medicines are disposed of appropriately, in accordance with regulatory and Environmental Protection Authority requirements, to reduce the potential for expired or unwanted medicines to be misused or for accidental poisonings.

The ACSQHC also leads and coordinates a range of national initiatives to reduce medication errors and harm, and to optimise medicines use. The ACSQHC has been engaged to review and update three national QUM publications related to the NMP by March 2022:

- [Guiding principles for medication management in residential aged care facilities](#);
- [Guiding principles for medication management in the community](#) and [reference guide](#);
- [Guiding principles to achieve continuity in medication management](#).

### ***Maintaining a responsible and viable medicines industry***

A responsible and viable medicines industry is critical to the development, manufacture, and supply of medicines. The NMP commits all parties to a coordinated and aligned approach between health and industry policy, to maintain a consistent and supportive environment.

The COVID-19 pandemic has highlighted the importance of an ongoing supply of medicines and the challenges in guaranteeing an uninterrupted supply chain. Medicine sponsors generally maintain continuity of medicine supply through demand forecasting, stock control, and back-up supply routes. However, despite their best endeavours, situations may arise where a disruption to the supply of a medicine cannot be avoided. Reduced medication availability can have serious equity, clinical and economic outcomes for patients. This includes potential increases in out-of-pocket costs, medication errors, adverse events, or increased risk of mortality during times of shortage.

This review will consider what high level considerations may need to be reflected within the NMP, to help offset and/or prevent such occurrences within a partnered approach recognising co-accountability.

**Question:**

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

## Terms of Reference 2: Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies.

The NMP currently considers the term “medicine” to include prescription and non-prescription medicines, including complementary healthcare products. The *Therapeutic Goods Act 1989* (TG Act) defines “medicine” as therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human. It also considers that medicines are those that do not fit the definition of therapeutic devices<sup>1</sup>.

The emergence of new drugs and novel medical technologies have the potential to alter the boundary between the term ‘medicine’ and ‘medical devices’. Feedback from the Stakeholder Forum raised the option of addressing medical devices within an expanded NMP. This view however was not universally held, with some participants highlighting the risk that an expanded policy would diminish the focus on medicines.

The TG Act defines medical devices as a wide range of products, such as medical gloves, bandages, syringes, blood pressure monitors, and X-ray equipment. These differ from medicines as they generally have a physical or mechanical effect on the body or are used to measure (or monitor) the body and its functions<sup>2</sup>.

The growing innovation of vaccinology towards therapeutic vaccines, specifically in cancer is also blurring the lines between prevention and treatment.

The intersection between medicines and medical devices, in particular, diagnostic tests, has implications for HTA processes. In Australia, HTA is defined as a range of processes and mechanisms that use scientific evidence to bring a considered and objective approach to determining the clinical benefit, safety, clinical effectiveness, and value for money of medicines and technologies. This aligns with international norms, including the definition of the World Health Organization (WHO)<sup>3</sup>. Many of the objectives contained in the NMP are applicable to medical devices, including that of maintaining safe affordable and equitable use.

### Questions:

- A. Should the current NMP definition of medicines be expanded to include medical devices and vaccines? Why or why not? How would a change in definition of medicines be reflected in the policy’s high-level framework?
- B. Does the policy’s current title, the “National Medicines Policy”, reflect the breadth of health technology developments within the policy’s scope? If not, how best can these and future health technologies be better represented in the policy’s title?

<sup>1</sup> <https://www.tga.gov.au/acronyms-glossary#summary-m>

<sup>2</sup> <https://www.tga.gov.au/medical-devices-overview>

<sup>3</sup> World Health Organization (2021) Health product and policy standards – Health technology assessment <https://www.who.int/teams/health-product-and-policy-standards/assistive-and-medical-technology/medical-devices/assessment>

## Terms of Reference 3. Assess the NMP's utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.

### The Health Policy Landscape

Australia's universal health system continues to embrace advancements in health care to deliver high-quality outcomes for all Australians. This is demonstrated at both the policy and practice level – with investments in cutting edge medical research and technologies that support new approaches for prevention, early detection, treatment, and recovery.

New treatments and therapies are expanding available treatment options. This includes novel biologicals, such as gene therapies, cell therapies and tissue-engineered medicines.

Simultaneously, policy frameworks and national reforms are underway to make the health system more person-centred, leverage digital solutions in health service delivery, and support a movement towards improving value and efficiency in the health system<sup>4</sup>. Recently, the COVID-19 pandemic has both accelerated and highlighted these developments at the health system, health service and individual levels. This has included considerations to support ongoing medicines supply in the context of global supply chain pressures; embracing the use of telehealth to support the delivery of health care; and a focus on empowering all consumers to acquire and apply health information about COVID-19 and vaccinations. These trends coincide with increased demand for health services associated with an ageing population and increased chronic disease burden.

### Precision Medicine

Significant advancements made in the fields of genomics, biotechnology and medical science are enabling new ways of identifying, preventing and treating disease<sup>5</sup>. As outlined in the 2018 Australian Council of Learned Academies report into 'The Future of Precision Medicine in Australia'<sup>6</sup>, Australia is well placed to harness these opportunities.

Precision medicine refers to the ability to consider the variability of an individual's genes, environment, and lifestyle to tailor a targeted approach to preventing, managing, and treating disease<sup>7</sup>. It represents a new frontier in healthcare. Key developments that have enabled advancements in precision medicine include:

- completion of the sequencing of the human genome and the accompanying developments that have enabled whole genome sequencing to be completed in days at a lower cost than originally required;
- increased data and analytical capacity and capability allowing association of genomic and related information with biomarkers, diagnosis, and clinical outcome; and

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<sup>4</sup> Value-based healthcare prioritises outcomes over outputs to maximise the achievement of outcomes that matter most to patients across the care pathway, at a cost that is acceptable to consumers and funders<sup>4</sup>. It also adopts a systems-approach to consider how all aspects of the health system can enable better value person-centred care. These health reforms, both in Australia and internationally, aim to address the growing pressures experienced through population changes. World Economic Forum. Shaping the Future of Health and Healthcare [Internet].

<https://www.weforum.org/platforms/shaping-the-future-of-health-and-healthcare>

<sup>5</sup> Williamson, R., Anderson, W., Duckett, SJ., Frazer, IH., Hillyard, C., Kowal, E., Mattick, JS., McLean CA., North, KN., Turner, A., Addison, C., (2018). The Future of Precision Medicine in Australia. Report for the Australian Council of Learned Academies, [www.acola.org.au](http://www.acola.org.au).

<sup>6</sup> Ibid.

<sup>7</sup> Mathur, S., & Sutton, J. (2017). Personalized medicine could transform healthcare. *Biomedical reports*, 7(1), 3–5. <https://doi.org/10.3892/br.2017.922>

- the continued evolution of medicines and vaccines including the use of viral subunits, gene strands and mRNA in new treatments or to support prediction, or prevention of disease strategies.

Further, [Australia's National Health Genomics Policy Framework](#) outlines a shared direction and commitment between all Australian governments to consistently and strategically integrate genomics into the Australian health system. This Framework is an agreed high-level national approach to policy, regulatory and investment decision-making for genomics. The Medical Services Advisory Committee (MSAC) currently considers genetic and genomic tests for public funding through the Medicare Benefits Schedule (MBS) as part of HTA processes.

Australia's continued investments in medical research, such as for cancers and rare diseases, and accelerating the use of precision medicines to support clinicians to provide targeted treatments that maximise efficacy and minimise side effects demonstrate how these opportunities are being harnessed. This includes the [Medical Research Future Fund \(MRFF\)](#), established by the Australian Government in 2015, to provide a long-term sustainable source of funding for Australian health and medical research that aims to improve health outcomes, quality of life, and health system sustainability. In July 2020, the MRFF grew to \$20 billion.

The translation of cutting-edge research into promising new treatment options can have significant benefits for patients, particularly those with high, unmet clinical needs. However, the breadth, complexity and speed these new treatment and therapy options are becoming available, raise both regulatory and reimbursement considerations. This has been raised in the [HoR Inquiry](#).

### **Clinical Trials and Medicines Access Programs**

Clinical trials and medicines access programs support the earliest access to novel treatments. Access to clinical trials and medicines access programs are not discussed in the current NMP. The Review will therefore need to consider what high level policy settings are required to ensure the significance of access to clinical trials and medicines access programs are appropriately reflected in the revised NMP.

### **Health Literacy**

Novel diagnostics and treatment options further emphasise the importance of a person-centric approach and relationships between patients, health providers and the industry. Health literacy is therefore critical. More complex treatment options suggest more effort will be needed to ensure consumers participate as partners in their treatments and care and are able to act on treatment advice and information provided. Empowering consumers must also go beyond creating consumer apps, digital health records, websites, or social media content. Research has shown that support must be provided to consumers to find, evaluate, and use health information effectively<sup>8,9</sup>. Results from the Health Literacy Survey, conducted by the Australian Bureau of Statistics in 2018 estimated that while the majority of people felt that they were able to appraise health information, almost 1 in 6 people disagreed or strongly disagreed that they are able to do so<sup>10</sup>. A strong association has been identified between some social determinants of health, such as lower level of education and socioeconomic status, older age, and being from a culturally and linguistically diverse background, with low health literacy which can compound the disadvantage experienced by marginalised groups. People with low health literacy are more likely to have

<sup>8</sup> Lee, K., Hoti, K., Hughes, J. D., & Emmerton, L. (2014). Dr Google and the consumer: a qualitative study exploring the navigational needs and online health information-seeking behaviors of consumers with chronic health conditions. *Journal of medical Internet research*, 16(12), e262.

<sup>9</sup> Australian Commission on Safety and Quality in Health Care. *Health literacy: Taking action to improve safety and quality*. Sydney: ACSQHC, 2014

<sup>10</sup> Australian Institute of Health and Welfare (23 July 2020). *Australia's health 2020: Determinants of health – health literacy*. <https://www.aihw.gov.au/reports/australias-health/health-literacy>

worse health outcomes overall and adverse health behaviours, such as (i) lower engagement with health services, including preventive services; (ii) higher hospital re-admission rates; (iii) poorer understanding of medication instructions (for example, non-adherence, improper usage); and (iv) lower ability to self-manage. Higher levels of health literacy are associated with increased patient involvement in shared decision making, which is important in patient-centred care<sup>11</sup>. The [Empowering people through health literacy reform under the 2020-25 National Health Reform Agreement \(NHRA\)](#) focuses on promoting person-centred health information and support to empower people to manage their own health and engage effectively with health services. This recognises that health literacy is a system issue, and a co-design approach is essential to support health professionals in delivering health-literacy responsive services, while providing consumers with the skills, knowledge, and motivation to fully participate and manage their health and healthcare.

The pandemic is also highlighting the importance of health literacy. The rollout of COVID-19 vaccines has made Australians, and people around the world, more aware of how medicines and vaccines are made available through their health system. This includes weighing up the risks and benefits when medicines are provided and recognising that medicines and vaccines, even the best of them, can have side effects for some individuals. These are important conversations, relevant to all medicine use. They remind us that the QUM is not only about safe and effective delivery. It is also about supporting and empowering consumers to build their understanding and knowledge of medicines use. This is increasingly important due to the proliferation of information and misinformation now available through social media.

Furthermore, there are particular population groups who may be disadvantaged by poor health literacy and more consideration is needed to tailor and target communication and increase access to language and literacy sensitive health and medicines information using diverse communications channels. Equity considerations also require addressing the financial and geographical barriers to accessing new treatment options.

### ***Equity and Sustainability***

The rapid acceleration of medical technology may also present equity and sustainability challenges. The high cost of adopting new innovations will need to be considered alongside the workforce and resourcing needs of the broader health system. This includes decisions concerning value for money, reimbursement and broader budgetary impact required to maintain a sustainable health system.

Many novel medicines have been associated with high, upfront costs including investment in the establishment of system infrastructure to support treatment delivery, in addition to the cost of the treatment itself. They are also often associated with significant practical service delivery considerations. This includes having the appropriate and adequate infrastructure and workforce capabilities to deliver these treatments, safely and effectively. This is seen in the current delivery of chimeric antigen receptor (CAR) T-cell therapy, where a small number of advanced hospital units in Australia have been equipped with the right expertise and infrastructure to deliver this highly specialised treatment. Financial and geographic barriers to access novel treatments may be an equity issue.

New therapies are increasingly opening up treatment options for rare diseases. The small population size and the lack of comparable treatment and outcome measures, often associated with rare diseases, may present challenges for the clinical trial design and the generation of the required cost-effective evidence, at a time of funding. This can present challenges when considering these new medicines in the context of the usual thresholds of cost-effectiveness and affordability considerations, at individual and societal levels<sup>12</sup>. The economic evaluations to

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<sup>11</sup> Ibid

<sup>12</sup> Lloyd-Williams, H., & Hughes, D. A. (2020). A systematic review of economic evaluations of advanced therapy medicinal products. *British Journal of Clinical Pharmacology*.

appraise these new medicines can also be challenged by the uncertainties in evidence generation for safety and quality data.

### **Real-World Evidence**

It has been argued that the use of real-world evidence to inform HTAs has the potential to address these evidence gaps relating to uncertainty. Real-world evidence does form a part of Australia's HTA decision-making process, with reimbursement programs, such as the Managed Access Program (MAP) framework available to support publicly funded access to new medicines based on preliminary evidence. Increased digital health capabilities will expand the capacity to generate real-world evidence. Data captured through digital health solutions could provide increased information to support reimbursement decisions, and ongoing monitoring of the safety and efficacy of treatments. However, these developments also raise data accuracy, privacy and ownership issues that need to be addressed in an equitable and transparent manner.

The Review will consider the high-level policy implications of utilising real time data collection and innovative digital technologies, to provide earlier access to new medicines and diagnostic technologies. These trends may bring greater equity of access, as new methodologies and systems of assessing effectiveness and outcomes emerge. This discussion will need to reflect on the growth of post market effectiveness assessments, post market surveillance and any transparency, privacy, and equity of access implications.

### **Drug Repurposing**

The [Therapeutic Goods Administration has also recently explored stakeholder views](#) on drug repurposing; where new uses are identified for existing medicines that are outside their original intended or approved medical use<sup>13</sup>. Equity of access to such therapies has been an issue and the current incentives and barriers are problematic. The identification of suitable compounds for use in both common and rare diseases can add to the potential treatment options available. There are also opportunities to leverage technological innovations, such as big data, artificial intelligence, and machine learning to supplement these therapeutic advancements.

These opportunities and challenges have been described by stakeholders in recent forums, including the [HoR Inquiry](#). The characteristics of emerging highly specialised treatments will require consideration in balancing faster and fairer access to new treatments, to meet social expectations, without compromising assessments on the safety, quality, and efficacy.

### **Digital health**

Digital health is delivering significant systems innovation and capacity improvements that is leading to improvements in health care delivery and health outcomes. A safe, seamless, and secure digital health environment can deliver significant benefits for patients. This is recognised in [Australia's National Digital Health Strategy](#).

Digital and social media have become a common source of information for consumers which has fuelled the exponential growth in the volume of readily accessible health-related information. This includes personal health information, aided through initiatives such as the [My Health Record](#), and NPS MedicineWise's [MedicineWise App](#). This has supported consumers to be better informed and support the self-management of their care<sup>14</sup>. These enablers mean consumer awareness of healthcare interventions, including their potential risks and benefits, are leading to more informed discussions with healthcare providers on appropriate treatment options.

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<sup>13</sup> Pushpakom, S., Iorio, F., Eyers, P. A., Escott, K. J., Hopper, S., Wells, A., ... & Norris, A. (2019). Drug repurposing: progress, challenges and recommendations. *Nature reviews Drug discovery*, 18(1), 41-58.

<sup>14</sup> Lee, K., Hoti, K., Hughes, J. D., & Emmerton, L. M. (2015). Consumer use of "Dr Google": a survey on health information-seeking behaviors and navigational needs. *Journal of medical Internet research*, 17(12), e288.

An increase in digitally enhanced models of care is also presenting new ways of engaging with health services, at a time and place convenient to consumers. This has been accelerated in part, by the COVID-19 pandemic, which has fast-tracked the availability of virtual based care, such as telehealth. Technology has also enabled a remodelling of health infrastructure, with the establishment of the first metropolitan virtual hospital in New South Wales ([rpavirtual](#)), which uses digital innovations to provide hospital type monitoring in the community underpinned by robust clinical models of care<sup>15</sup>. The progressive rollout of ePrescribing and electronic prescriptions has also promoted increased convenience for consumers. This initiative also has the potential to improve patient safety through reducing risks of transcription errors. While these initiatives have expanded access, there is a need to ensure that the digital divide<sup>16</sup> does not compromise equal access to healthcare, irrespective of place and location.

**Questions:**

- A. How has the NMP been able to maintain its relevance and respond to the changes in the health landscape?**
- B. How could the NMP be refreshed so that the policy framework is able to better address current and future changes in the health landscape? What is missing and what needs to be added to the policy framework, and why?**

#### **Terms of Reference 4: Consider the centrality of the consumer within the NMP and whether it captures the diversity of consumers' needs and expectations.**

The NMP emphasises the fundamental role of the consumer in achieving the policy's four objectives and identifies responsibilities for consumers in its discussion on making the partnership work. Australia is a culturally and geographically diverse nation, yet there is no acknowledgement in the NMP of the diversity of consumers and their specific needs. It also adopts a more passive approach to consumer engagement that relies on 'ensuring consultation with consumer representatives when new arrangements are contemplated'.

Discussions at the Stakeholder Forum emphasised the need for a patient-centric focus within the NMP to empower consumers to make informed choices about the QUM. This sentiment was widely held. The strengthening of the consumer voice and input in the policy was raised as an important principle.

An updated policy will need to recognise that consumers are becoming more active and informed participants in their care and broader health policy. This is articulated in key documents, such as the [Australian Charter of Healthcare Rights](#) which describes what consumers, or someone they care for, can expect when receiving healthcare. Increased consumer engagement has in turn, led to increased expectations of governments, health services and health professionals to build both individual health literacy and create health literacy environments. This can be achieved through:

- building culturally appropriate person-centred health environments which promote the achievement and maintenance of health and wellbeing;

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<sup>15</sup> Shaw M, Anderson T, Sinclair T, Raffan F, Dearing C, Hutchings O and Jagers D. (2020). Deeble Perspectives Brief No 13: rpavirtual: a new way of caring. Australian Healthcare and Hospitals Association, Canberra, Australia.

<sup>16</sup> Organisation for Economic Co-operation and Development (OECD) Glossary of statistical terms: Digital Divide. Accessed from: <https://stats.oecd.org/glossary/detail.asp?ID=4719>

- promoting understanding and engaging consumers as active, empowered, and informed participants in their care;
- providing prompt, appropriate, targeted, and tailored support to achieve optimal health outcomes;
- promoting equity of access to timely and affordable treatment, when, where and how it is needed.

Feedback presented in the Stakeholder Forum, raised the importance of consumer health literacy in understanding and implementing the QUM, as described in the previous section. Many participants proposed that health literacy should be explicitly included in the NMP, and also emphasised the need for consumer education as an enabler to be a focus of the updated policy.

The emergence of new treatments, particularly for conditions which have high unmet need, has also changed consumers' expectations in relation to their ability to access timely and affordable treatments. This has been raised through submissions and public hearings of the [HoR Inquiry](#).

The consumer voice is increasingly being incorporated into the decision-making processes relating to the approval and public funding of new medicines and technologies.

This has included representation and advocacy by key patient organisations, and progressive structural improvements to facilitate consumer engagement and involvement. Initiatives to support this include:

- Consumer representation on key health technology assessment (HTA) committees and expert panel. This includes the PBAC and its Drug Utilisation and Economic Sub Committees, the Medical Services Advisory Committee (MSAC), the Life Saving Drugs Program Expert Panel, and the Australian Technical Advisory Group on Immunisation (ATAGI);
- Consumer representation on TGA Advisory Committees, such as the [Advisory Committee on Medicines](#) and the [Advisory Committee on Medical Devices](#). These committees provide independent medical and scientific advice, as well as advice on appropriate consumer health issues relating to medicines.
- Establishment of the [HTA Consumer Consultative Committee](#) in 2017 – to provide strategic advice and support to HTA principal committees and the Department of Health to support consumer involvement and understanding of HTA processes and decision making;
- Establishment of the [HTA Consumer Evidence and Engagement Unit](#) in the Department of Health in 2019 – to support the development of structured projects of engagement with consumer and patient groups; and
- Enhancing the autonomy of Aboriginal Community Controlled Health Services to provide culturally appropriate delivery of services.

These structural enhancements are supporting greater consumer awareness of and participation in HTA processes. However, evidence from the [HoR Inquiry](#) indicates that consumers desire greater transparency in relation to the decision-making process.

**Question:**

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

## Terms of Reference 5: Identify options to improve the NMP's governance; communications, implementation (including enablers) and evaluation.

In its discussion on making the partnership work, the NMP identifies partners or groups of partners with responsibilities for advancing each of the four objectives. The discussion consists of a high-level list of outcomes that partners are responsible for delivering under each objective and emphasises the importance of collaboration and interrelationships between each objective.

The medicines policy landscape has matured since the NMP was published in 2000. Formal agreements between key partners and inter-governmental funding agreements between Commonwealth and State Governments have been secured.

To support the implementation of the PBS in public hospitals, from 2001 the Commonwealth entered into bilateral Pharmaceutical Reform Agreements (PRAs) with all states and territories except New South Wales and the Australian Capital Territory. The PRAs permit approved public hospitals to prescribe and dispense PBS-subsidised medicines and chemotherapy drugs to day-admitted patients, outpatients, and patients upon discharge<sup>17</sup>.

The [Nationally Cohesive Health Technology Assessment reform under the 2020-25 NHRA](#) provides specific arrangements to ensure Australians with some of the rarest conditions have access to new, life-saving highly-specialised therapies in public hospitals. The [2020-25 NHRA](#) also includes a commitment by all governments to work together on long-term system wide reforms, which aim to provide person-centred care in the most appropriate setting.

Program specific NMP Administrative and Advisory structures have continued and support outcomes across the NMP's objectives. The Committees and organisations listed below leverage existing resources to raise and address NMP issues. They also ensure that specific issues are progressed in a targeted way by the NMP partner best placed to do so. These structures include:

- The [PBAC and its sub-committees](#), and [ATAGI](#) provide recommendations on the listing of medicines and vaccines on the PBS and the National Immunisation Program (NIP). These bodies provide a range of advice on issues relating to the QUM, economic funding, disease burden including epidemiological advice, medicines scheduling, and other medicines use considerations.
- The [TGA's statutory advisory committees and other committees](#) that provide independent expert advice on specific scientific and technical matters.
- Post-Market Review Reference Groups to provide expert advice on issues, including guidelines, QUM, efficacy, and cost-effectiveness and other medicines use issues, related to a specific PMR.
- Australian Medicines Working Group, Generic Medicines Working Group, Pharmaceutical Industry Working Group (with the Department of Industry) and Pharmaceutical Industry Discussion Group. These committees can advise on issues associated with access and the viability of the medicines industry and serve as a forum for industry to raise and discuss issues with the Department.
- The National Medicines Symposium (organised by NPS) is currently held biennially and provides a forum for stakeholders to discuss NMP related issues and present current research, particularly with respect to the QUM.

As a result of these developments, the implementation of the NMP has become more complex. Feedback presented in the Stakeholder Forum highlighted the need to address potential fragmentation, reduce duplication, and ensure greater transparency and accountability for all partners involved in the policy's implementation.

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<sup>17</sup> PBS Pharmaceutical Hospital Review Final Report 2017. Page 3 [17 PBS Pharmaceuticals in Hospitals Review Final Report, December 2017. Page 3](#)

## Communication and engagement

Consumer and stakeholder engagement with medicines policies and the HTA processes have strengthened over time. This has resulted in a need for timely, targeted, and transparent communications.

Improved communications, including clear links between various policies and initiatives that are associated with the NMP, would reduce the perception of fragmentation and lack of coordination relating to medicines policy in Australia. The NMP is not prescriptive about the programs and processes used to deliver on its objectives. Ensuring clear links to the NMP are communicated could promote public recognition of a strategically aligned approach and promote visibility of the key partners and their work in delivering the NMP's objectives.

Further, there is an opportunity to consider how two-way exchange of information for stakeholders to raise and consult on specific NMP issues can be better facilitated. This may be explored through leveraging established structures of consultation, such as the current processes in place to support comments on submissions to the PBAC, or in response to PMRs.

### **Questions:**

- A. What opportunities are there to strengthen governance arrangements for the NMP? What would these be, and why?**
- B. How can communication about the NMP be enhanced or improved?**
- C. What would be effective mechanisms to support communication about the policy?**

## Terms of Reference 6: Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.

The importance of a partnership approach is stressed throughout the NMP. The achievement of its objectives relies on the partners listed under each objective working together to implement the policy. The document acknowledges the challenges associated with delivering an integrated approach but stops short of providing direction on how to manage these tensions, beyond a partnership-based approach. This is reflective of the document's status as an overarching principle-based framework.

The following groups are represented in the NMP as having responsibilities for advancing the policy's objectives:

- healthcare consumers, their carers, and the general community;
- health practitioners, health educators and professional organisations;
- Commonwealth, state, territory and local governments;
- medicines industries;
- peak bodies including partners in collaborative agreements for identified groups, including Aboriginal and Torres Strait Islander people;
- healthcare funders and purchasers such as private health insurers; and
- media.

Under the NMP, each partner is responsible for their own contribution towards the policy's objectives. The document also notes the importance of collaboratively developing mechanisms to

assess progress against the policy's objectives 'to hold parties accountable for progress in areas where they have an identified responsibility'.

Feedback from the Stakeholder Forum indicated support for a more structured, transparent and accountable evaluation process to inform an understanding of the gaps and opportunities to monitor the delivery of the NMP's core objectives. To varying degrees, performance is being measured at the program or initiative-level. As an example, the publication of PBS data, and timeframes for listing of new medicines, report the Department of Health's achievements in relation to the policy's objective to timely access to medicines. System-level measurements, such as the National Indicators for QUM in Australian Hospitals 2014<sup>18</sup> have also been established. These indicators, developed by the ACSQHC with the NSW Therapeutic Advisory Group, support measurement of safety and the QUM in acute settings. ACSQHC has also been tasked with developing the National Baseline Report on Quality Use of Medicines and Medicine Safety as part of the Government's commitment to making Quality Use of Medicines and Medicine Safety the 10<sup>th</sup> National Health Priority. Measurement of health outcomes gathered through patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs) in the Australian context have been suggested as needing to be explored.

The reliance on multiple partners working collaboratively to deliver the NMP objectives highlights the importance of establishing strong accountability measures. The tensions described in relation to the policy's implementation persist and feedback from the Stakeholder Forum called for higher levels of transparency, including the management of conflict of interests. The importance of transparency and accountability, especially in relation to partnerships involved in implementing the policy, was also raised as a critical principle.

Feedback from the Stakeholder Forum also highlighted a need for greater strategic alignment across medicines policy priorities, and a need for greater transparency and accountability from the NMP partners in their delivery of the policy's objectives.

**Questions:**

- A. How should the NMP's 'partnership-based' approach be defined?**
- B. What is missing from the policy's reference to the NMP partners? Are there other partners that should be included in the policy? Who would they be and why?**
- C. How could the NMP be refreshed to support greater accountability amongst the NMP partners? How could the partnership approach be improved?**
- D. How are conflicts of interest currently managed and should more be done to address this amongst the NMP partners? What approaches could be taken?**

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<sup>18</sup> Australian Commission in Safety and Quality in Health Care (2021). [National Indicators for Quality Use of Medicines \(QUM\) in Australian Hospitals 2014](#). Accessed 19 January 2021.

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All information in this publication is correct as at August 2021