Consultation Draft - National Medicines Policy

Overview

Published in 2000, Australia's National Medicines Policy (NMP) is a well established and universally endorsed framework that aims deliver positive health outcomes for all Australians through their access to, and appropriate use of, medicines. The NMP guides the range of activities encompassing medication management, access and affordability of medicines in Australia through a partnership approach between all sectors.

The Review of the NMP (the Review) was commissioned by the Minister for Health, the Hon. Greg Hunt MP in recognition of the substantial changes to the health landscape since the policy was published in 2000.

The Review has been led by an Expert Advisory Committee established by the Minister for the Department of Health. The Committee is chaired by Deputy Chief Medical Officer, Professor Michael Kidd AM. Its members include Professor Lloyd Sansom AO; Mrs Janette Donovan; Dr Sarah Dineen-Griffin and Mr David Herd. This Committee has brought expertise across medicines policy, clinical practice, consumer engagement and the pharmaceutical industry to the Review.

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

The refreshed draft Policy contains central pillars and principles, that direct the identification, design, development and evaluation of policies, strategies, programs, and initiatives that advance equitable, safe, timely and affordable access to medicines. It also identifies key policy enablers and connects them to related health and industry policies. The revised draft NMP also outlines a governance and evaluation approach that acknowledges that success is dependent on all Policy partners and the community playing their part in fostering a medicine policy environment geared to responding to current and new challenges for the benefit of all Australians.

Development of the draft NMP

The Committee undertook a 12-week period of public consultation that commenced on 30 August 2021 and concluded on 17 November 2021. The public consultation process included a call for public submissions, and bilateral interviews and virtual group discussions with selected stakeholder organisations. The Committee also held a virtual stakeholder webinar forum in December 2020 to present the key themes from the consultation process. The Review Committee received 156 written submissions and consulted with 194 representatives across 135 organisations through its program of meetings and virtual group discussions. Further information about the now closed consultation, including the Discussion Paper, can be found here: https://consultations.health.gov.au/technology-assessment-access-division/national-medicines-policy-review/>

Drawing on this extensive engagement process, and diversity of views expressed, feedback received has been used to inform the refresh of the NMP as a high-level policy framework. The draft policy reflects stakeholders' recognition of the continuing relevance of the policy's objectives and affirmed the importance of a person-centred and partnership-based approach. It also captures the changes in the health system environment, where applicable, to ensure that the Policy remains relevant now and into the future.

Why your views matter

The NMP Review Committee invites your feedback on the draft National Medicines Policy. The diverse perspectives, experience, and knowledge of all stakeholders, including members of the community, are valued and will contribute to the final Policy.

Consultation Information

The draft Policy found at the bottom of the page is open for consultation via the Consultation Survey. The survey will close on Tuesday 16 February 2022. Late submissions or requests for extension will not be accepted.

About the Survey

The survey is structured into 8 parts. These parts reflect the structure of the refreshed Policy.

The survey sections and the number of questions include:

- Section 1. Privacy information (2 questions)
- Section 2. Introduction (6 questions)
- Section 3. Scope, aim, principles and enablers (4 questions)
- Section 4. Governance (1 question)
- Section 5. Central Pillars (4 questions)
- Section 6. Implementation (1 question)
- Section 7. Evaluation (1 question)
- Section 8. General Comments

If you wish, you can complete the survey in stages by using the 'save and return' feature. At the bottom of each survey page, you can select the 'Save and come back later...' button. You will then be asked to provide an email address. A unique link will be emailed to you that will allow you to return where you left off. Email addresses entered for this purpose are not saved with your responses to the survey.

You will need to answer 'required' questions before you can submit your response.

How will responses be used?

Findings from the survey will be collated and used to inform refinements to the draft Policy.

To download a copy of the draft Policy, click on >> and select 'Download'.



Draft National Medicines Policy Consultation Draft

Privacy and your personal information

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.

Each submission and comment, except where supplied in confidence, will be considered for publication on the Department's website, and if published, remain indefinitely as a public document. If you consent, the information in your submission (other than a respondent's personal contact information) may be published on the Department's website. Submissions that are published on the Department's website can be assessed by the general public, including people overseas. Ordinarily, where the Department discloses personal information to an overseas recipient, Australian Privacy Principle (APP) 8.1 requires the Department to take reasonable steps to ensure that the overseas recipient does not breach the APPs. However, if you consent to the publication of your submission, APP 8.1 will not apply to this disclosure and the Department will not be accountable under the Privacy Act for any subsequent use or disclosure by an overseas recipient of the personal information contained in your submission, and you will not be able to seek redress under the Privacy Act.

Further, 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 </https://www.legislation.gov.au/Details/C2020C00366 </https://www.legislation.gov.au/Details/C2020C00366 </https://www.legislation.gov.au/Details/C2020C00366 </https://www.legislation.gov.au/Details/C2020C00366 </https://www.legislation.gov.au/Details/C2020C00366 </https://www.legislation.gov.au/Details/C2020C00366 </https://www.legislation.gov.au/Details/C2020C00366 </https://www.legislation.gov.au/Details/C2020C00366 </html>

The Department has an APP privacy policy which you can read at https://www.health.gov.au/resources/publications/privacy-policy https://www.health.gov.au/resources/publications/privacy-policy https://www.health.gov.au/resources/publications/privacy-policy https://www.health.gov.au/resources/publications/privacy-policy 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.

You can contact the Department regarding its privacy policy by telephone on (02) 6289 1555 or freecall 1800 020 103 or by using the online enquiries form at https://www.health.gov.au/about-us/contact-us#general-enquiries https://www.health.gov.au/about-us/contact-us#general-enquiries .

1 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

(R	eq	uire	d)

Please select only one item

Ο	Yes
\bigcirc	No

2 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. Do you consent?

(Required)

Flease se	lect only one item	
	, I consent	

No, I do not consent

3 Please read and agree to the below declarations:

By making a submission, I acknowledge that:

- I understand that the giving of my consent is entirely voluntary.
- I am over the age of 18 years.
- · I understand the purpose of the collection, use, publication, or disclosure of my submission
- Where relevant, I have obtained the consent of any individuals whose personal information is included in my submission, and consent to the Department collecting this information for the purposes outlined in this notice.
- I understand that, where I have provided consent to my submission being published, the Department has complete discretion as to whether my submission, in full or part, will be published.

I have read, understood and consent to the above statements. (Required)

Introduction

4 What is your name?

(Required)

5 What is your email address? If you enter your email address then you will automatically receive an acknowledgement email when you submit your response.

What is your email address?

6 Are you responding as an individual or on behalf of an organisation?

(Required)

Please select only one item

As an individual

On behalf of an organisation

- 7 What is the name of your company and/or organisation? (If applicable)
- 8 Which of the following options best matches the area of interest for you and or/your organisation?

(Re	Required)					
Pleas	Please select all that apply					
	Medical professionals					
	Pharmacists					
	Nurses					
	Medicines industry					
	Medical technologies and/or medical devices industry					
	Consumer, including carer or consumer representative					
	Academic					
	Medical research, including clinical trials					
	Policy and program delivery					

- Other
- **9** May we contact you to ask you for more information, or to seek feedback on how the consultation was undertaken?

(Required)

Please select only one item

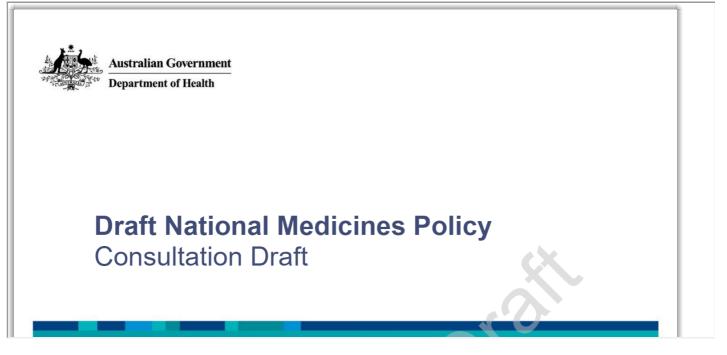


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How to respond

To be able to answer these questions, you must first read the Draft National Medicines Policy - Consultation Document. To download a copy of the draft Policy, click on >> and select 'Download'.

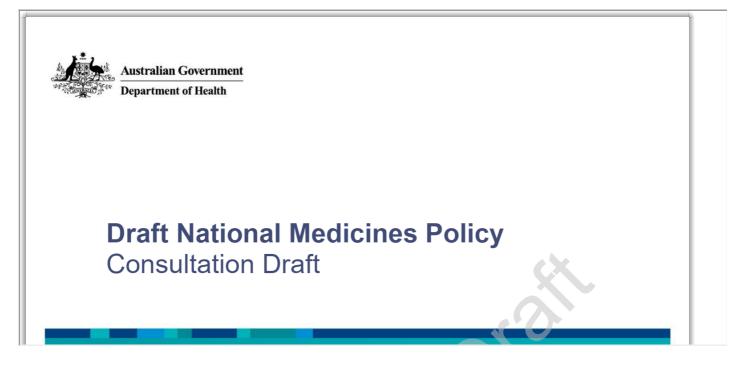
Please submit your views by answering the questions in this survey. This will step you through the questions seeking specific feedback.



Aim, scope, principles and enablers

The following questions will seek your feedback on the Policy's aim, scope, principles and enablers.

These sections can be found on pages 2-5.



10 Aim

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

Using the scale below, please indicate your level of agreement with the Policy's aim.

(Required)
Please select only one item
Strongly Agree
Agree
Neither Agree nor Disagree
Disagree
Strongly Disagree

You can explain your selection or provide comments in the text box below if you wish. (1000 Words)

11 Scope

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

This broad scope ensures the policy is adaptive and responsive to new and emerging treatment options. It also recognises that the definitions of medicines may vary across Commonwealth, state and territory legislation and regulation. Notwithstanding, the Policy's principles and pillars are applicable to all the above products and their clinical use as well as being applicable to relevant future advanced therapies. The Policy's scope can be found on pages 2-3.

Using the scale below, please indicate your level of agreement with the Policy's scope.

(Required) Please select only one item Strongly Agree Agree Neither Agree nor Disagree Disagree Strongly Disagree

You can explain your selection or provide comments in the text box below if you wish. (1000 Words)

12 Principles

The Policy includes key principles, that should be evident in the planning, design and implementation of all policies, strategies, programs, and initiatives related to the Policy. These can be found on page 4.

Using the scale below, please indicate your level of agreement with the inclusion of each of the Policy's Principles and their descriptions.

(Required)	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Person-centred Please select only one item	0	0	0	0	0
Equity Please select only one item	0	0	\bigcirc	0	0
Partnership-based Please select only one item	0	0	0	0	0
Accountability and transparency Please select only one item	0	\bigcirc	0	0	0
Shared responsibility Please select only one item	0	0	0	0	0
Innovation Please select only one item	0	0	0	0	0
Evidence-based Please select only one item	0	0	0	0	0
Sustainability Please select only one item	\bigcirc	0	\bigcirc	0	\bigcirc

You can provide further comments in the text box below if you wish. (1000 Words)

13 Enablers

The NMP influences, and is also influenced by, related policies, programs, and initiatives of the wider health system. Seven enablers are identified in the Policy as being critical to the Policy's success. These can be found on page 5.

Using the scale below, please indicate your level of agreement with the inclusion of each of the Policy's Enablers and their descriptions.

(Required)	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Health literacy Please select only one item	0	0	0	0	0
Leadership and culture Please select only one item	0	\bigcirc	0	0	0
Health workforce Please select only one item	0	0	0	0	0
Research Please select only one item	0	0	0	0	0
Data and information Please select only one item	0	0	0	0	0
Technology Please select only one item	0	0	0	0	0
Resources Please select only one item	0	0	\bigcirc	0	\bigcirc
ou can provide further comments	in the text box below if you wish. (1000 Words)			

Governance

The Policy describes a governance approach that is focused on co-ordination and shared problem solving and accountability. It also recognises that each partner is responsible and accountable for achieving the NMP's aim and intended outcomes.

The Policy's governance section can be found on pages 7-8.



Draft National Medicines Policy Consultation Draft

14 Using the scale below, please indicate your level of agreement with the proposed governance.

(Required)

Please select only one item

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

You can explain your selection or provide comments in the text box below if you wish (1000 Words)

Central Pillars

The Policy includes four Central Pillars. The function of these pillars is to guide and focus collective actions to deliver the Policy's aim. Each of these Pillars includes intended outcomes associated with their realisation, a description of the Pillar including their related components, and key responsible partners.

The Central Pillars can be found on pages 9 - 20.



Draft National Medicines Policy Consultation Draft

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

Using the scale below, please indicate your level of agreement with the Pillar, including its intended outcome, description and key responsible partners.

(Required)
Please select only one item
O Strongly Agree
Agree
Neither Agree nor Disagree
Disagree
Strongly Disagree
Please select the relevant sections of the Pillar below should you wish to provide additional comments.
Please select all that apply

Intended Outcome

Description

Key responsible parties

Additional Comments (1000 Words)

16 Pillar 2: "Medicines meet appropriate standards of quality, safety and efficacy."

Using the scale below, please indicate your level of agreement with the Pillar, including its intended outcome, description and key responsible partners.

(Required)
Please select only one item
Strongly Agree
Agree
O Neither Agree nor Disagree
Disagree
Strongly Disagree
Please select the relevant sections of the Pillar below should you wish to provide additional comments.
Please select all that apply
Intended outcome
Description
Key responsible partners
Additional Comments (1000 Words)

17 Pillar 3: "Quality use of medicines and medicines safety."

Using the scale below, please indicate your level of agreement with the Pillar, including its intended outcome, description and key responsible partners.

(Required)

Please select only one item

Strongly Agree

O Agree

Neither Agree nor Disagree

O Disagree

Strongly Disagree

Please select the relevant sections of the Pillar below should you wish to provide additional comments.

Please select all that apply

Intended outcome

Description

Key responsible partners

Additional Comments (1000 Words)

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

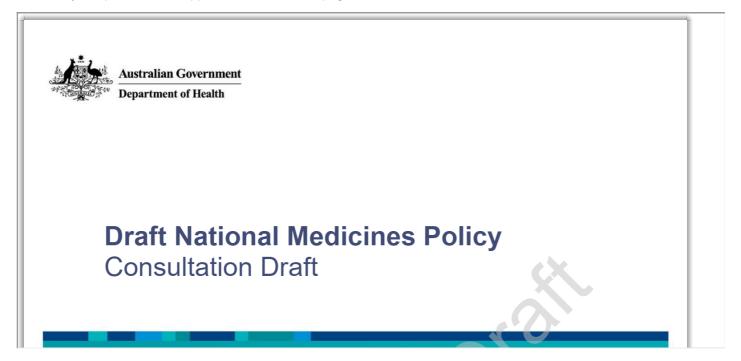
Using the scale below, please indicate your level of agreement with the Pillar, including its intended outcome, description and key responsible partners.

(Required)
Please select only one item
Strongly Agree
Agree
Neither Agree nor Disagree
Disagree
Strongly Disagree
Please select the relevant sections of the Pillar below should you wish to provide additional comments.
Please select all that apply
Intended outcome
Description
Key responsible partners
Additional Comments (1000 Words)

Implementation

The NMP functions as a co-ordinating framework that sets out the Pillars and intended outcomes for all partners to work towards. As no single partner can be completely responsible for achieving the policy's aim, its implementation approach is a collective responsibility appropriately documented at the program level by each partner.

The Policy's implementation approach is outlined on pages 21 - 22.



19 Using the scale below, please indicate your level of agreement with the proposed implementation approach.

(Required)
Please select only one item
Strongly Agree
Agree
O Neither Agree nor Disagree
Disagree
O Strongly Disagree
You can explain your selection or provide comments in the text box below if you wish. (1000 Words)

Evaluation

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

The Policy's evaluation approach, including guidance for components of an evaluation strategy aligned to the NMP is outlined on page 23.

Australian Government Department of Health Draft National Medicines Policy Consultation Draft **20** Using the scale below, please indicate your level of agreement with the proposed evaluation approach.

(Required)
Please select only one item
O Strongly Agree
Agree
Neither Agree nor Disagree
Disagree
Strongly Disagree
You can explain your selection or provide comments in the text box below if you wish. (1000 Words)

General Comments

21 Please provide any additional comments you may have on the draft Policy.