

# Response ID ANON-YB7E-2HWS-U

Submitted to National Medicines Policy - consultation on the revised NMP  
Submitted on 2022-09-27 14:54:23

## Introduction

1 What is your name?

Name:  
Nicole Millis

2 What is your email address?

Email:  
nicole.millis@rarevoices.org.au

3 What is your organisation?

Organisation:  
Rare Voices Australia

## 1. Privacy information

1.1 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?

Yes, I consent

1.2 If you consent, the Department may, at its discretion, publish part or all of the information or all of the information provided in your submission on the Department's website and 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 Please note that your email address will not be published, and responses may be moderated to remove content that is inappropriate/offensive or contains sensitive information.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?

Yes, I consent

1.3 Please read and agree to the below declarations. By making a submission, I acknowledge that I have read, understood and consent to the following statements: 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; and 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.

## 2. Introduction

2.1 What is your name?

Full name:  
Nicole Millis

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

Email address:  
nicole.millis@rarevoices.org.au

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

Organisation

2.4 What is the name of your company and/or organisation (if applicable)?

Name of organisation:  
Rare Voices Australia (RVA)

2.5 Which of the following groups best represents you/your organisation's interest? If you/your organisation belong to more than one, please select the most accurate.

Representative group:

Other

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

Yes

### 3. Vision, aim, scope, principles and enablers

3.1 Vision The Policy's vision is to 'achieve the best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment.' This vision will be achieved through an effective partnership environment. The vision can be found on page 2. Using the scale below, please indicate your level of agreement with the Policy's vision.

Neither agree nor disagree

Agreement with Policy vision comments:

The wording "highly supportive medicines policy" is quite vague and unclear. It would be good for Vision to also reference/ highlight principles of equity; as well as include future-looking language around innovation.

Overall, RVA does not think it is critical to include a Vision statement, especially as the revised Aim is now quite strong and clear.

3.2 Aim The aim of the Policy has been updated to simplify the language and provide clarity to reflect stakeholder suggestions. The Policy's aim 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.

The updated aim can be found on page 2. Using the scale below, please indicate your level of agreement with the Policy's aim.

Strongly agree

Comments on Policy aim:

No further comment

3.3 Scope The scope of the NMP has been broadened to include reference to medical devices used in the delivery of medicines and medicines-related services, and the reference to Aboriginal and Torres Strait Islander traditional medicines has been strengthened. The revised draft NMP refers to 'medicine' as covering 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 scope ensures the policy can adapt and respond to new and emerging treatment options. It also recognises that the definitions of medicines may vary across Commonwealth, state and territory legislation and regulation. The Policy's principles and Pillars are applicable to all the above products and their clinical use. The Policy's scope can be found on page 2. Using the scale below, please indicate your level of agreement with the Policy's scope.

Strongly agree

Comments on Policy scope:

No further comment

3.4 Principles The principles have been refined to include greater detail on what the principles mean in action. Notable changes include:

- The principle of equity is now 'equity and access'.
- Partnership-based and shared responsibility are now one principle.

Using the scale below, please indicate your level of agreement with each of the Policy's Principles and their descriptions. These can be found on pages 6-7.

Person-centred – strongly agree

Equity and access – strongly agree

Partnership-based and shared responsibility – strongly agree

Accountability and transparency – strongly agree

Innovation – strongly agree

Evidence-based – agree

Sustainability – agree

3.5 Enablers The NMP influences, and is also influenced by, related policies, programs, and initiatives of the wider health system. The list of enablers were supported by stakeholders and have been updated to reflect feedback, including further clarity under the description of the enabler. The updated enablers can be found on page 7. Using the scale below, please indicate your level of agreement with the inclusion of each of the Policy's enablers and their descriptions.

Health literacy – agree

Leadership and culture – strongly agree

Health workforce – strongly agree

Research – strongly agree

Data and information – strongly agree

Technology – strongly agree

Resources – agree

#### 4. Central pillars

4.1 Pillar 1 Timely, equitable and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford. Using the scale below, please indicate your level of agreement with Pillar 1, including its intended outcome and description. If you wish to provide additional comments on the relevant sections of this Pillar, please use the free text box below.

Strongly agree

Comments on Pillar 1 sections:

Under 'Affordability and value-based healthcare':

"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."

Please remove "where appropriate" as PROMS are always appropriate.

Under 'A supportive and responsive industry and medicines research environment':

Effective collaboration between governments, health care 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."

Patient/ consumer-led groups play a significant role in this, especially in rare disease, yet are not mentioned as collaborators here. They need to be acknowledged as a partner here. As it is currently written, it is difficult to see how it is 'person-centred'.

4.2 Pillar 2 Medicines meet the required standards of quality, safety and efficacy. Using the scale below, please indicate your level of agreement with Pillar 2, including its intended outcome and description. If you wish to provide additional comments on the relevant sections of this Pillar, please use the free text boxes below. Intended outcome (250-word limit); Description [1,000-word limit].

Strongly agree

Comments on Pillar 2 sections:

No further comment.

4.3 Pillar 3 Quality use of medicines and medicines safety. Using the scale below, please indicate your level of agreement with Pillar 3, including its intended outcome and description.

Strongly agree

Comments on Pillar 3 sections:

No further comment.

4. 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. Using the scale below, please indicate your level of agreement with Pillar 4, including its intended outcome and description. If you wish to provide additional comments on the relevant sections of this Pillar, please use the free text boxes below. Intended outcome (250-word limit); Description [1,000-word limit].

Agree

Comments on Pillar 4 sections:

It would be good to also include clinical workforce here.

## 5. Partnerships – achieving the NMP's vision and aim

5.1 Figure 1 – Centrality of individuals, carers, families and communities, and the relationships between the NMP partners Figure 1 demonstrates how the NMP influences the relationships between identified key partners and individuals, carers, families and communities. Using the free text box below, please indicate if there are any partners missing from Figure 1 on page 3. Response option [Free text – 200 word limit].

Figure 1 comments:

No further comment.

5.2 Pillar 1 Timely, equitable and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford. Using the scale below, please indicate your level of agreement with the partnership approach, including the key responsible partners. The key responsible partners for Pillar 1 can be found on pages 16-17. You may provide further comments in the text box below if you wish.

Disagree

Comments on Pillar 1 partnership approach:

RVA supports the revised draft's concept that implementation is the collective responsibility of all partners. To make this robust however, RVA strongly suggests adding another responsibility/ function to all partners related to pillar 1:

- commitment to measure, highlight and address gaps/challenges/ barriers to timely, equitable and reliable access to medicines

5.3 Pillar 2 Medicines meet the required standards of quality, safety and efficacy. Using the scale below, please indicate your level of agreement with the partnership approach, including the key responsible partners. The key responsible partners for Pillar 2 can be found on pages 17-18. You may provide further comments in the text box below if you wish.

Disagree

Comments on Pillar 2 partnership approach:

RVA supports the revised draft's concept that implementation is the collective responsibility of all partners. To make this robust however, RVA strongly suggests adding another responsibility/ function to all partners related to pillar 2:

- commitment to measure, highlight and address gaps/ challenges/ barriers to quality, safety and efficacy

5.4 Pillar 3 Quality use of medicines and medicines safety. Using the scale below, please indicate your level of agreement with the partnership approach, including the key responsible partners. The key responsible partners for Pillar 3 can be found on pages 18-19. You may provide further comments in the text box below if you wish.

Disagree

Comments on Pillar 3 partnership approach:

RVA supports the revised draft's concept that implementation is the collective responsibility of all partners. To make this robust however, RVA strongly suggests adding another responsibility/ function to all partners related to pillar 3:

- commitment to measure, highlight and address gaps/ challenges/ barriers to quality use of medicines and medicine safety.

5.5 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. Using the scale below, please indicate your level of agreement with the partnership approach, including the key responsible partners. The key responsible partners for Pillar 4 can be found on pages 20-21. You may provide further comments in the text box below if you wish.

Disagree

Comments on Pillar 4 partnership approach:

RVA supports the revised draft's concept that implementation is the collective responsibility of all partners. To make this robust however, RVA strongly suggests adding another responsibility/ function to all partners related to pillar 1:

- commitment to measure, highlight and address gaps/ challenges/ barriers to a responsive, innovative and sustainable medicines industry and research sectors

5.6 Governance Framework The revised draft NMP maintains a description of a governance approach that embraces partnership. It has been updated to be described as a framework to better reflect a governance approach that is focused on co-ordination and shared problem solving and accountability, rather than being prescriptive about specific structures. It also recognises that each partner is responsible and accountable for achieving the NMP's aim and intended outcomes. The Policy's governance framework can be found on page 22. Using the scale below, please indicate your level of agreement with the Policy's governance. You may provide comments in the text box below if you wish.

Disagree

Comments on Policy's governance:

The Governance section is somewhat stronger in this revised draft. RVA notes that the revised draft NMP also includes consistent references on the need for the Policy's partners to communicate alignment of their programs, initiatives or activities with the NMP, including how they have put the principles into action. For this to be robust however Governance should also recognise the need to also regularly report on gaps and limitations (opportunities for improvement!) and communicate on how these will be addressed and prioritised. This is particularly important for rare disease and other priority populations potentially requiring more targeted and equitable responses.

**5.7 Implementation** The revised draft NMP remains consistent with the idea that 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 is solely responsible for achieving the Policy's aim, its implementation is a collective responsibility that should be documented appropriately at the program level by each partner. This could include better alignment between policy, legislation and regulatory frameworks across different levels of government. The Policy's implementation is outlined on page 22. Using the scale below, please indicate your level of agreement with the Policy's implementation. You may provide comments in the text box below if you wish.

Disagree

Comments on Policy's implementation:

RVA welcomes the revised draft wording:

"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. "

However, this does not go far enough. The development of policies, services, programs etc should not just require identification of whether they are consistent with the pillars and principles of the NMP, but also require identification of where there are gaps or areas of misalignment with the NMP and how this will be addressed.

**5.8 Evaluation** The revised draft NMP describes beneath each Pillar the intended outcomes that the partners should collectively strive to achieve. The Committee updated the evaluation section to reiterate the importance of a partnership approach to evaluation and the need to better align policies, strategies, programs, and initiatives that underpin the NMP. The Policy's evaluation, including guidance for components of an evaluation strategy aligned to the NMP, is outlined on page 22. Using the scale below, please indicate your level of agreement with the Policy's evaluation. You may explain your selection or provide comments in the text box below if you wish.

Disagree

Comments on the Policy's evaluation:

While RVA notes that the evaluation section in the revised draft has improved it still does not clearly outline who will evaluate the NMP and how it will be evaluated. Again what is also missing from this section is a commitment to proactively measure, highlight and address gaps, challenges and barriers. RVA notes the inclusion of 'Guidance for an evaluation strategy aligned to the NMP' This should also include the following: What are the gaps? How are we measuring gaps, challenges, barriers?

## 6. General comments

**6. General comments** Please provide any additional comments you may have on the revised consultation draft 2022 NMP.

General comments on revised consultation:

Thank you for the opportunity to provide comment. This revised draft policy is much improved and clearly reflects consideration of stakeholder feedback, including RVA input.

RVA welcomes the reference and alignment of the NMP to the National Strategic Action Plan for Rare Diseases.