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Submitted to Consultation Draft - National Medicines Policy
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Privacy and your personal information

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

2 • If you consent, the Department may, at its discretion, publish part 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 Please note that your email address will not be published, and responses may be moderated to remove content that is inappropriate/offensive or contains sensitive information.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

3 Please read and agree to the below declarations:

I have read, understood and consent to the above statements.:
Yes

Introduction

4 What is your name?

What is your name? :
Nicole Millis

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?:
nicole.millis@rarevoices.org.au

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

On behalf of an organisation

7 What is the name of your company and/or organisation? (If applicable)

What is the name of your company and/or organisation? (If applicable):
Rare Voices Australia

8 Which of the following options best matches the area of interest for you and or/your organisation?

Other

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

Yes

How to respond

Aim, scope, principles and enablers

10 Aim

Disagree

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

The Aim is excessively wordy and unclear. RVA strongly recommends revision of this Draft Aim into a separate Vision and Aim as follows:

Vision: Improved health, social and economic outcomes are secured for individuals and the broader community

Aim: The Policy's aim is to achieve appropriate structures and processes to facilitate equitable, safe, timely and affordable access to quality medicines and medicines related services for all Australians.

11 Scope

Agree

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

RVA supports the broadened scope which importantly now includes medical research and cell and gene therapies.

The Australian Government's National Strategic Action Plan for Rare Diseases
notes that "for many people living with a rare disease, participation in a clinical trial may be the only way to access treatment." Cell and gene therapies have the potential to transform rare disease care. The emergence of cell and gene therapies, precision medicine, as well as an increase in co-dependent technologies has led to complexity in these therapies navigating existing regulatory and reimbursement pathways, especially when such therapies are delivered in a hospital environment. This broader definition of medicines should help to reduce the uncertainty regarding HTA processes and potentially reduce delays in access.

12 Principles

Policy Principles - Person-centred:
Agree

Policy Principles - Equity:
Agree

Policy Principles - Partnership-based:
Neither Agree nor Disagree

Policy Principles - Accountability and transparency:
Agree

Policy Principles - Shared responsibility:
Neither Agree nor Disagree

Policy Principles - Innovation:
Agree

Policy Principles - Evidence-based:
Neither Agree nor Disagree

Policy Principles - Sustainability:
Neither Agree nor Disagree

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

RVA strongly recommends the inclusion of two further principles 'timeliness' and 'fit for purpose'. A principle of 'timeliness' would more accurately reflect its critical importance to all stakeholders, particularly to patients/consumers. Timeliness is critical for the rare disease community. Many rare diseases are progressive and access to medicines is time critical. Uncertainty about when a decision regarding a health technology will be reached adds to the burden already experienced by those living with a rare disease, as well as their families and carers. Delays in access to medicines is serious in rare disease and leads to poor, sometimes grave, health outcomes for people.
The inclusion of timeliness as an NMP principle would facilitate a much-needed focus on further defining what is meant by terms such as "timely access" and identify potential ways that timeliness can be measured. Recent evidence points to deficiencies in the timeliness of reimbursement in Australia. The Compare 5 report by Medicines Australia (2019) reported that, "It takes roughly three to four times longer for New Molecular Entities (NMEs) to achieve reimbursement in Australia (410 days) than world leaders Japan (98 days), Germany (119 days), Austria (148 days) and
Switzerland (149 days)". Arguably, on average, Australians living with a rare disease wait even longer. The Funding Rare Disease Therapies in Australia – Ensuring Equitable Access to Health Care for All Australians report by The McKell Institute (2014) reported that "Australians are generally waiting from 2 to 4 years longer for access to rare disease therapies available in comparable countries". Over the last five years, RVA has provided mentorship to individual rare disease patient groups, much
of which focuses on their participation in health technology assessment (HTA). From this work, RVA has learned that multiple submissions are often required before a rare disease medicine is recommended for reimbursement. Similarly, from our work with the RVA Round Table of Companies, a group of pharmaceutical companies with a common interest in rare diseases and orphan drug development, RVA is aware that companies that submit applications for rare disease indications typically anticipate that it will take more than one submission to achieve reimbursement. This perception alone is damaging as it deters companies from applying and contributes to Australia failing to be identified as a priority market. This whole situation is horrifying to the individual Australian who needs access to medicine now. The inclusion of a timeliness timeliness principle is an initial key step to disrupt and transform this.

An NMP fit for purpose principle would enable policy settings to better respond to rare diseases, and align with a key action of the National Strategic Action Plan for Rare Diseases: Action 2.4.2: Ensure funding and reimbursement pathways are fit-for-purpose and sustainable for current and new health technologies for rare diseases.

The inclusion of this principle would help guide agreements and processes to better
respond to transformative therapies such as cell and gene therapies, precision medicine, co dependent technologies and drug repurposing. A fit for purpose principle would also equip the NMP to better respond to the evidentiary challenges that come with these new and emerging technologies, as well as the ongoing evidentiary challenge inherent in the rare disease context generally.

13 Enablers

Policy Enablers - Health literacy:
Agree

Policy Enablers - Leadership and culture:
Agree

Policy Enablers - Health workforce:
Agree

Policy Enablers - Research:
Agree

Policy Enablers - Data and information:
Agree

Policy Enablers - Technology:
Agree

Policy Enablers - Resources:
Agree

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

Governance

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

Disagree

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

As the NMP is such a key policy the governance section needs to be significantly strengthened. It calls for collaborative work from all partners but does not outline a structure to support this. Indeed all the draft NMP really achieves in this area is a listing of the different partners/ stakeholders but does not define relationships. The Panel stated that this was due to them not wanting to prescribe what the types of relationships. However by not addressing this, the NMP fails to even acknowledge, let alone address power and knowledge imbalances and significant COIs between partners/ stakeholder groups. The draft NMP states it is person-centred and includes a diagram with people/ consumers at the centre, yet fails to acknowledge the inherent imbalance of HTA which inherently prioritises negotiations between commercial sponsors and the Department and where patients/ consumers as well as clinicians only have a secondary role. RVA strongly recommends the establishment of an overarching governance committee to oversee the policy's implementation and reviews, and to provide advice where required. The committee must be consumer-centric in having equal numbers of consumers to clinicians, researchers, administrators, and other stakeholders, and include a diverse mix among all committee members. Diversity must be fundamental in both the compiling of this policy and in its governance. The consumers on the committee need to be selected from among those with good consumer connections, who are actively involved in or with consumer organisations, community organisations or other active consumer-based involvement. There also must be underpinning mechanisms to support consumers in their role on the committee, particularly in facilitating them in consulting with a broader range of consumers. Clear terms of reference and transparent processes are also vital.

Central Pillars

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

Disagree

Description

Additional Comments (1000 Words):

This Pillar is not strong enough and does not provide the right policy setting to enable timely, equitable or reliable access.

The policy simply provides motherhood statements and very basic list of partners/ stakeholders and very brief outline of their broad responsibilities. This Pillar fails to guide and focus collective actions.

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

Disagree

Description

Additional Comments (1000 Words):

This Pillar is not strong enough and does not provide the right policy setting to enable medicines meet appropriate standards of quality, safety and efficacy.

The policy simply provides motherhood statements and very basic list of partners/ stakeholders and very brief outline of their broad responsibilities. This Pillar fails to guide and focus collective actions.

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

Disagree

Description

Additional Comments (1000 Words):

This Pillar is not strong enough and does not provide the right policy setting to enable the quality use of medicines and medicine safety.

The policy simply provides motherhood statements and very basic list of partners/ stakeholders and very brief outline of their broad responsibilities. This Pillar fails to guide and focus collective actions.

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

Disagree

Description

Additional Comments (1000 Words):

This Pillar is not strong enough and does not provide the right policy setting to achieve a responsive and sustainable medicines industry and research sector with the capability, capacity and expertise to meet current and future health challenges.

The policy simply provides motherhood statements and very basic list of partners/ stakeholders and very brief outline of their broad responsibilities. This Pillar fails to guide and focus collective actions.

Implementation

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

Strongly Disagree

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

The draft NMP section on Implementation is very brief and contains vague language eg 'create the environment'. It fails to identify the specific areas, systems or steps that are needed. It includes a diagram of examples of implementation mechanisms but this is merely a brief list of programs.

The Panel stated that as the NMP is a high level policy, KPIs are not appropriate as they are too prescriptive. However the current draft section on Implementation is alarmingly ineffective. To truly embed its policy principles the NMP needs to provide further direction regarding implementation. There are other ways to do this other than specific KPIs. The NMP needs to provide the higher level implementation direction/ settings to enable the most appropriate KPIs to be developed by partners. The Implementation section should identify Key Result Areas - general metric or parameters that do not prescribe outcomes but that are fixed and further articulate the NMP Principles. The NMP should outline the major areas that require exceptional performance and need extra monitoring/ evaluating eg general metrics relating to consumer involvement; general metrics relating to timeliness etc.

Evaluation

20 Using the scale below, please indicate your level of agreement with the proposed evaluation approach.

Strongly Disagree

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

The Evaluation approach is even briefer and weaker than the Implementation Section. It is vital that the NMP has a clearly articulated evaluation approach that is designed to reflect the principles of the NMP itself, in particular,person-centred, accountable and transparent, and evidence based. Instead the draft NMP outlines an evaluation approach that is less than half a page and brief list.

It does not even respond to the basic key questions of:
Who will evaluate the NMP?
How will the NMP be evaluated?

When the NMP will be evaluated?

General Comments

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

General comments:

Thank you for considering RVA's original submission and for meeting with us, as well as this opportunity to comment. RVA can see parts of our input reflected in the NMP draft. We welcome the included paragraph on the complexities of rare diseases. RVA particularly welcomes the broadening of scope of the NMP and the inclusion of 'innovation' as a principle.

We are very concerned however that the the current NMP draft will not meet its potential due to the grossly underdeveloped implementation and evaluation sections. RVA acknowledges the Panel's reluctance to be over-prescriptive and wary of the contextual use of KPIs, however as a result, the draft NMP runs a real risk of being ineffectual and not enabling the high level policy settings required. This will have a flow on effect to other related policy, systems and structures, as well as negative impacts on Australians. RVA calls for the identification and inclusion of key result areas and general metrics to help translate the NMP principles which can then be further customised and contextualised at the program level. RVA would be very happy to discuss further.