

NATIONAL MEDICINES POLICY

Response to the Draft

March 2022



ABOUT RESEARCH AUSTRALIA

We are the national peak body representing the whole of the health and medical research pipeline.

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our goals:

Engage

Australia in a conversation about the health benefits and economic value of its investment in health and medical research.

Connect

researchers, funders and consumers to increase investment in health and medical research from all sources.

Influence

government policies that support effective health and medical research and its routine translation into evidence-based practices and better health outcomes.

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NATIONAL MEDICINES POLICY

RESPONSE TO THE DRAFT

Introduction

The draft National Medicines Policy (NMP) has been developed by the Expert Advisory Committee and draws on the consultations conducted by the Group in 2021. The consultation on the Draft NMP was conducted via an electronic survey. Responses to each question were subject to restrictions on the number of words allowed. Research Australia's response to the electronic survey is reproduced below. The response to the first nine questions provided identifying information and have not been reproduced below.

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.

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

Agree

Research Australia notes the focus on **creating the environment** for, rather than **actually implementing** the structures, processes and accountabilities to support the provision of medicines. This is appropriate and helps to define what the policy is, and what it is not. The clarity of this Aim is not always evident in the rest of the document, for example when the NMP assigns responsibility for specific actions to one or more partners.

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.

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

Agree

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.

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

Person-centred - Agree

Equity - Agree

Partnership-based - Agree

Accountability and transparency - Agree

Shared responsibility - Agree

Innovation - Agree

Evidence-based - Agree

Sustainability - Agree

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.

13. 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 - Agree

Health workforce - Agree

Research - Agree

Data and information - Agree

Technology - Agree

Resources - Agree

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.

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

Disagree

The purpose of the Governance section in the NMP is unclear. The immediate assumption is that it will address governance for the NMP itself- for example, which body will have oversight of the NMP. However, this is not the case; instead, it appears to specify some conditions and requirements for the 'Governance structures, including specific committees and working groups (which) may be established for the policies, strategies, programs, and initiatives aligned with the NMP.' (The term 'aligned' is vague.)

These various conditions and requirement conditions are:

- 'Appropriate consumer representation at all levels of governance' of aligned governance structures to demonstrate their commitment to person-centred care
- some broad statements about the importance of accountability, transparency, and managing conflicts of interest
- a requirement to be person-centred.

The following statement seems to conflate the NMP itself, mechanisms for setting shared priorities and the governance structures without providing any clarity about the relationship between these three.

'Mechanisms that support collaborative action and timely application of the efforts and expertise of relevant partners in setting shared priorities are vital to the Policy's success. Therefore, these structures should monitor the achievements against the Pillars of the NMP, including reporting on how the NMP's principles have been put into action.'

The new draft NMP has expanded the number of 'partners' in the NMP; this includes incorporating researchers as partners, which Research Australia supports. However, apart from identifying a specific role for the Commonwealth in relation to governance, the NMP assumes that all the other partners have similar responsibilities and capabilities when it comes to governance of the NMP and/or the aligned policies, strategies, program and initiatives; and that 'each partner is responsible and accountable for achieving the NMP's aim and intended outcomes'.

This is not the case. While the Commonwealth is a single entity and has responsibility and accountability for the NMP, many other partners (individuals, carers, health practitioners) don't have responsibility for the NMP and cannot be held accountable for it.

Furthermore, many of the designated partners are not a single identifiable entity. For example, 'researchers' are multiple different entities and individuals, and will play a range of different roles. And while Figure 2 purports to show the relationship between the different partners, it doesn't do any more than list them all, and emphasise the primacy of 'individuals, carers, families and communities'.

It is not clear from the Governance section how researchers, a disparate group, could be held accountable for delivery of the NMP, and the same is true of many other partners. In fact, to the extent there is accountability for the role played by researchers in the NMP, it is unlikely to come through governance structures of the NMP or its aligned policies, strategies, programs and initiatives. It is more likely, it seems, to come through established processes around research integrity and processes for the conduct research and for the dissemination of research findings.

Research Australia suggests the section on Governance be reconsidered, including its purpose, and that an effort be made to outline the roles and responsibilities of the different partners for governance in the same manner that the different roles have been identified for each partner under the Pillars. This would include identifying the partners that **do not** have responsibility for governance functions.

Research Australia also proposes considering the merger of the Governance and Implementation sections of the NMP, as there currently appears to be significant overlap between the two.

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.

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.

Agree

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

- ◇ Intended Outcome
- ◇ Description
- ◇ **Key responsible parties**

Research has a particular role to play in creating an evidence base for change and improvement; and helping the system remain relevant, take advantage of technological and other advances, and respond to demographic change and disease burden.

Relevant disciplines include health services and systems researchers, demographers, pharmacologists, pharmacoepidemiologists and other epidemiologists, informatics and big data researchers.

In addition to the existing role for researchers outlined for this Pillar, researchers can play a role in investigating whether the outcome of timely, equitable and reliable access is being met; in

identifying communities and subgroups for which this is not the case, and helping to develop solutions (policy, new distribution mechanisms etc.). There is also a role for research to develop new and better means of supporting consumer engagement and participation.

Researchers can help the policy framework with responding to chronic conditions, comorbidity, polypharmacy, and understanding interactions with the socioeconomic determinants of health. Research can also help guide the design, implementation and evaluation of new programs and policy to improve timely, equitable and reliable access.

Data on medicines use can be better utilised to make the NMP more consumer centric. Other data (MBS, hospital, health insurance) can also be utilised to better understand medicines use in a more consumer centric way. Researchers have a key role to play in investigating this data.

A consumer centric approach will allow us to better understand timeliness and equity of access, variations in use, preferences across all types of medicines: prescription and non-prescription; subsidised versus non-subsidised; and conventional versus complementary and alternative.

Although safety nets and PBS subsidies might prevent substantial economic hardship, many patients still face financial barriers substantial enough to affect adherence to treatment – resulting in presentable complications and hospitalisations. Medicines data can help understand these barriers, the consequences, and what can be done to address them.

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

Agree

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

- ◇ Intended Outcome
- ◇ Description
- ◇ **Key responsible parties**

Additional Comments (1000 Words)

Only a very limited role for researchers is identified in respect of Pillar 3, dealing with the development of drugs and post market safety monitoring and reporting.

There is a further role for research in the ongoing improvement and development of standards, for example around the safe use of classes of medicines, and for new models of quality assurance in regards to quality, safety and efficacy. This includes investigation of Australia's Health Technology Assessment framework to identify areas for improvement in the standards that are set and the models by which these standards are enforced and monitored.

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

Agree

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

- ◇ Intended Outcome
- ◇ Description
- ◇ **Key responsible parties**

Additional Comments (1000 Words)

No role for researchers is identified in respect of Pillar 3.

How do consumers make decisions about different prescription and non-prescription medicines, and how could information be better presented to them to support their decision making? The COVID-19 epidemic has highlighted the different sources of information that influence decisions about whether to be vaccinated and about treatments for COVID-19.

While there has been some research undertaken in Australian and internationally into how consumers make decisions about medicines, more research is needed to understand how to support better decision making by consumers about the medicines they use and how they use them.¹² By paying particular attention to disadvantaged and minority groups, the involvement of researchers can support the NMP in relation to the principle of Equity.

The role of research in informing activities to support Quality Use of Medicine should be explicitly recognised in the NMP. Much more could be done in partnership between the Department, researchers, health practitioners and consumers to refine policy and guidelines for the use of medicines and support interventions at the patient-practitioner interface as well as at the population level. The Veterans MATES Program is a useful case study as to what can be achieved by a partnership between researchers, government, health practitioners and patients to improve the quality use of medicines and medicines safety.³

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

Agree

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

- ◇ Intended Outcome
- ◇ Description
- ◇ **Key responsible parties**

¹ <https://www.safetyandquality.gov.au/our-work/partnering-consumers/shared-decision-making/decision-support-tools-consumers>

² Lisa M. Schwartz, Steven Woloshin and H. Gilbert Welch, The Drug Facts Box: Providing Consumers with Simple Tabular Data on Drug Benefit and Harm, *Med Decis Making* 2007 27: 655 originally published online 14 September 2007, available at <http://mdm.sagepub.com/content/27/5/655>

³ <https://www.unisa.edu.au/research/qumprc/>

Research Australia welcomes the focus on the Australian medicines industry and research sector and the critical issue of capability, capacity and expertise.

The Government has identified Medical Products as a priority area. A broad category, this includes, for example, pharmaceutical products. Australia already has world class research to support the development of new medicines and pharmaceuticals.

In 2019, global exports of pharmaceutical products accounted for USD582 billion. 20 of the world's nations accounted for 92% of this total, valued at USD534 billion. The world's Number One exporter of pharmaceutical products was Germany at USD89.4 billion, with 15.3% of global pharmaceutical exports. Number 23 was Australia, with exports of USD3.2 billion, or 0.55% of global exports.⁴

In the same year (2019), Australia imported pharmaceutical products valued at \$USD7.38 billion, or 1.27% of global pharmaceutical imports.⁵

Pharmaceutical manufacturing, including vaccines and serums, is a sensible area for Australia to seek to expand its capability. It is an area where security of supply is paramount; it is also an area where we have existing expertise in manufacturing and world leading expertise in life sciences that we can leverage. It is a growing market, and one where capability is relatively well dispersed around the developed world.

While Australia has research and manufacturing capabilities in specific areas, we do not currently have the breadth and depth of capabilities, capacity and expertise to support a larger, sustainable medicines industry.

While recognition of the importance of this pillar is welcome, it is unclear how the NMP will support or influence the further development of this Pillar.

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.

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

⁴ Sourced 23 November 2021 from

<https://atlas.cid.harvard.edu/explore?country=undefined&product=129&year=2019&productClass=HS&target=Product&partner=undefined&startYear=undefined>

⁵ Sourced 23 November 2021 from

<https://atlas.cid.harvard.edu/explore?country=undefined&product=129&year=2019&tradeDirection=import&productClass=HS&target=Product&partner=undefined&startYear=undefined>

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

Disagree

As noted above, there appears to be significant overlap between the Governance and Implementation sections, and this causes confusion about the respective purposes of these two sections.

Once again, the NMP treats each partner as a single individual/entity. This is not the case with researchers, and we do not understand how the following paragraph can or would be applied to researchers.

‘Each partner should communicate the linkages between their actions, connection to the Pillars and the implementation of the NMP’s Principles, to support collective understanding of what is being done to achieve the policy’s aims and achieving the agreed outcomes.’

Further guidance is required about the role of researchers in the implementation of the NMP, but Research Australia doubts that it is appropriate or possible to outline the role for researchers in the same way that the NMP outlines the role of the Government in Figure 3.

The NMP also states ‘All partners are encouraged to map out the areas where they can deliver and/or influence action according to their remit. Achievement of the policy’s aims and outcomes is the collective responsibility of all partners.’

While Research Australia accepts that the partners have ‘collective responsibility’ for the NMP we don’t believe it is ‘equal responsibility’ or that it is appropriate to leave it to the individuals to ‘map out the areas where they can deliver and/or influence action’. Research Australia submits that this mapping exercise should be undertaken collectively and should be identified as a suitable implementation action for the NMP, to be led by the Department of Health.

Research Australia notes that in Figure 3 ‘Health research funding’ is identified as a Government ‘mechanism for implementation’ of the NMP. While the Australian Government currently funds health and medical research, and we welcome the policy intent expressed in Figure 3, there is currently no program or other means to implement this policy intent through existing research funding programs such as the Medical Research Future Fund or the National Health and Medical Research Council’s funding programs. Research Australia would welcome the opportunity to work with the Department further on how a stream of research funding can be created to support the NMP.

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.

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

Disagree

In addressing Evaluation, the NMP has once again failed to adequately consider the expanded and disparate group of partners it has included in the draft NMP and the distinct roles they play. The section seems to be aimed at the partners that have responsibility for the 'policies, strategies, programs, and initiatives aligned with the NMP.' Research Australia believes this is some, rather than all of the partners, and that a process is needed to further define the roles of the respective partners before the NMP can proceed. This includes clarifying which partners have **responsibility** for Governance, Implementation and Evaluation functions, and which have a role in **supporting** Governance, Implementation and Evaluation activities.

20 General Comments

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

As a document that provides guidance and principles to be implemented through other policy measures, Research Australia accepts that there is a necessary tension in the NMP between being so high level that it is not meaningful and being so prescriptive that it becomes outdated and stifles innovation.

In some areas, such as the Pillars and the recognition of the breadth of partners, the NMP has found the appropriate balance. In other areas, such as trying to specify roles for partners, particularly in relation to Governance, Implementation and Evaluation, the balance has not been achieved.

From our own review of the document and conversations with our membership and the broader HMR community, it is clear that there is still significant confusion and dissatisfaction with the draft NMP.

Research Australia believes the NMP needs considerably more work, and that further consultation is required before the NMP is finalised, recognising that this may take some time. We believe that the NMP warrants this additional time and work, as it sets the framework for better health as well as greater economic opportunities from a stronger domestic medicines industry.

END OF SUBMISSION

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