



The Pharmacy
Guild of Australia

PHARMACY GUILD OF AUSTRALIA

Submission: Draft National Medicines Policy

2 March 2022

National Secretariat

Level 2, 15 National Circuit, Barton ACT 2600
PO Box 310, Fyshwick ACT 2609
P: +61 2 6270 1888 • F: +61 2 6270 1800 • E: guild.nat@guild.org.au
www.guild.org.au



SUBMISSION QUESTIONS

Note: Sections 1 and 2 are introductory questions about privacy and contact details, so have not been included below.

Section 3: Scope, aim, principles and enablers

To be able to answer these questions, you must first read the [Draft National Medicines Policy - Consultation Document](#).

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

Question 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:

- Agree

You can explain your selection or provide comments below if you wish. (1000 words):

The precepts of the Aim in the draft National Medicines Policy (the Policy) are suitable.

The Pharmacy Guild of Australia (the Guild) notes that the sentence is 67 words long, and that the language used is fussy and complicated and may not be readily comprehended. We recommend that the text of the aim should be edited to improve readability.

Question 11: Scope

The Policy's scope refers to the term 'medicine' which 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:

- Agree

You can explain your selection or provide comments below if you wish. (1000 words):

The Guild agrees with the scope presented in the draft National Medicines Policy. We support the inclusion of vaccines, gene therapies and cell and tissue engineered products in the policy.

We note that, in defining the term 'medicine', the draft policy references an Australian Government Department of Health website. We fear that such a reference could be easily changed, perhaps even inadvertently. If a reference is necessary on this page, we believe it should be drawn from either a contemporary Australian dictionary (e.g. Macquarie, Collins) or the World Health Organization.

We particularly note that a range of reproductive medicines, including oral, injectable and implantable contraceptives, fertility stimulants, and agents used for medical termination of pregnancy, are not encapsulated by the description contained in the draft policy. I.e. they are not "... products that are used to prevent, treat, monitor, or cure a disease." We recommend revising this description to incorporate all such medicines, for instance by adding a phrase such as "... or otherwise enhancing physical or mental welfare.

The Guild requests that the term "over-the-counter medicine" be deleted from the draft policy and replaced with the term "non-prescription medicine". The continued use of the term "over-the-counter" carries with it an implication that potent medicines may be purchased on-demand and without oversight, intervention and counselling from qualified health professionals such as pharmacists. Classifying medicines as either prescription or non-prescription is consistent with the breadth of regulatory and scheduling controls in Australia, but does not diminish the provision and appropriate use of medicines to that of a simple transaction.

With the new broader definition of medicines, the Guild notes that all medicines must be funded in a way that does not negatively impact consumers, prescribers or pharmacies. For example, currently many medical devices are not funded as part of the PBS, however if the Australian Government were to fund more medical devices through the PBS, additional funds would need to be committed to accommodate this to avoid a significant overspend of PBS funds. This new broader definition of medicines will require a discussion and commitment from government to additional funding sources, as the PBS is not currently designed to fund this broader definition of medicines.

Question 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:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Person-centred				✓	
Equity					✓
Partnership-based				✓	
Accountability and transparency				✓	
Shared responsibility				✓	
Innovation				✓	
Evidence-based				✓	
Sustainability				✓	

You can provide further comments below if you wish. (1000 words):

The Guild agrees with the inclusion of the principles, particularly the principle of equity, because affordability of medicines is a key contributor to equity of access.

We call for the addition of a further principle: "Responsive" or "Dynamic" to be added as a principle. to reflect the dynamic nature of medicine usage and health demands in Australia.

The fast-paced nature of development of medicines, vaccines, and medical devices, as well as changes in consumer preferences and population health challenges, demand that the National Medicines Policy should be dynamic and responsive. The addition of such a principle would encourage partners, including government bodies, to regularly consider the currency of the NMP and address any inconsistencies between the NMP and current practice.

We recommend that the following principles are refined (additions or changes are underlined):

- The last sentence of the Person-centred principle should be amended to read: "This includes a focus on building health literacy, so that individuals, carers, their families, and the broader community are supported to be informed and active participants in decision-making and medicine usage."
- The last sentence of the Equity principle should be amended to read: "These groups include, but are not limited to, Aboriginal and Torres Strait Islander people, people from culturally and linguistically diverse backgrounds, those living in rural and remote areas, older people, those living with a disability, and other vulnerable groups.

Question 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:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Health literacy					✓
Leadership and culture				✓	
Health workforce					✓
Research				✓	
Data and information				✓	
Technology				✓	
Resources				✓	

You can provide further comments below if you wish. (1000 words):

The Guild agrees with the inclusion of these enablers and their descriptions. We recommend refining the Health Workforce enabler to read as follows (additions are underlined):

“a competent workforce that is accessible and sufficiently resourced to provide co-ordinated and integrated care and is enabled to work to their full scope of practice, across all health settings applying applicable and relevant best practice guidelines which are regularly updated to consider the clinical place of new technologies.”

It may also be beneficial for the Health Workforce enabler to mention the need for empowered and sufficiently resourced health practitioners, including community pharmacists, to support culturally and linguistically diverse (CALD) consumers and others who may have a lower level of health literacy such as consumers from lower socio-economic backgrounds. There is a great opportunity for community pharmacists, as highly accessible and knowledgeable health professionals, to support CALD consumers and those with low health literacy in relation to their medicines, and this applies to both the Health Workforce and the Health Literacy enablers.

Section 4: Governance

Question 14: 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.

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

- Disagree

You can explain your selection or provide comments below if you wish. (1000 words):

The Guild believes that the governance section of the draft Policy lacks specific detail, and that the language used in the section is full of "waffle words".

For instance, the following words lack meaning:

"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."

Figure 2 is simplistic, and while it identifies some of the partners of the NMP, it does not "illustrate the relationships between the partners".

The Governance section does not describe how adherence to the policy will be monitored, nor the method and frequency for reviewing and updating the policy.

We recommend that the governance section makes explicit the responsibilities of Commonwealth and State and Territory Governments in funding and coordinating programs, guidelines and schemes. For instance, (changes are underlined):

"In this context, the role of the Commonwealth and State and Territory Governments is to fund and coordinate programs, guidelines and schemes, to lead and encourage collaboration between partners toward shared goals, and to promote transparency in relation to accountability, reporting and communication. This includes facilitating collaborative action on problems that cannot be solved by any one partner."

Finally, as mentioned elsewhere in our submission, this section in particular merits careful editing to apply the "clear language and writing style" expectations of the Australian Government Style Manual.

Section 5: 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.

Question 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:

- Description

Additional comments:

The Guild agrees with the text of Pillar 1, however we recommend that changes are made to the accompanying text:

- We recommend removing the text "within the constraints of limited budgets" as it devalues the aim of this pillar to achieve equitable access to medicines.

The Guild supports the cost-benefit evaluation of listing medicines to the PBS, however where a favourable cost-benefit is demonstrated the medicine should be added to the PBS without delay. Governments should not hesitate because the sticker price makes them nervous. The listing of protease inhibitors to treat hepatitis C virus are a recent example of a class of medicines that may not have been PBS listed if "limited budgets" were a foremost consideration.

- The following sentence should be amended to reflect the difficulty that rural Australians sometimes have in accessing medicines (addition underlined): "Access is also an equity issue. Australia is a diverse nation and people can experience inequity of access to health care and to medicines because of their identity, background, location or personal circumstance."
- The Policy should make a clearer commitment to both the timeliness of medication listings and availability. The onus should be placed on the Commonwealth Government to ensure that Australia is not one of the last countries in the OECD to have a new medicine listed by its regulator, or publicly funded for the benefit individuals in need.
- In addition to supporting "Efficient and effective distribution and supply networks" the Policy should recognise the need for investment in and support of Australia's health workforce (in particular prescribers and pharmacists) to support timely, equitable and reliable access to medicines.
- The Policy should recognise the successful, safe and responsible overseas models of pharmacist prescribing. The Guild believes that more timely access to medicines across all Australian communities can be provided by enabling pharmacists to prescribe within their scope of practice with clear protocols and specific prescribing rights.

Question 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:

- 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:

The Guild agrees with Pillar 2: "Medicines meet appropriate standards of quality, safety and efficacy" and its intended outcomes.

Question 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:

- Neither agree nor disagree

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

- Intended outcome
- Description
- Key responsible parties

Additional comments:

The Guild partly agrees with the selection of Pillar 3: "Quality use of medicines and medicines safety."

We believe that the intended outcome overlooks the role that health professionals play in the quality use of medicines and medicine safety, and recommend additional dot points such as:

- "Health professionals are supported in the evidence-based selection and prescribing of medicines"
- "Frameworks and programs are in place to monitor the quality use of medicines and to identify and address medicine safety risks"

Building on these two additional outcomes we seek to have the professional activity of medication review recognised within the National Medicines Policy.

We recommend specifically identifying the critical role that real-time prescription monitoring systems play in reducing harm from opioids and illicit drug precursors. This can be achieved by adding the underlined text to the following section:

"Efforts by all partners to minimise the risk of harm from the overuse, underuse and misuse of medicines is crucial. This includes a particular focus on reducing antimicrobial resistance, monitoring, and responding to inappropriate polypharmacy and the deprescribing of unnecessary medicines, reducing harm from high-risk medicines and improving medication safety in all settings including at transitions of care. National real-time prescription monitoring is critical to reducing harm from high-risk medicines at risk of abuse or misuse."

The Guild acknowledges that Pillars 2 and 3 now benefit from specifically mentioning the terms "prescribing, dispensing and administration" of medicines, and the removal of the ambiguous term "retail supply" from the Policy. We emphasise that the role and responsibility of dispensing medicines is greater than simply "supplying" them, and the term "supply" should not be used where "dispense" would be more accurate. On page 17 we request adding the term "dispensing" to the following text: "prescribing, dispensing, supply, administration and deprescribing of medicines". Prescription medicines are not a retail commodity that can be supplied through "efficient pricing" regimes.

With Quality Use of Medicines and Medicines Safety a National Health Priority, the Guild has concerns that supply of potent medicines outside of the community pharmacy channel represents a substantial risk to patient and community safety. We call upon the Policy to identify the community pharmacy network as the Australia's preferred method of dispensing and supply of prescription and non-prescription medicines.

The Policy should also include reference to the trend towards personalised medicine and the opportunities it presents for therapeutic optimisation and reduction in adverse events, in particular through advances in pharmacogenomics. The Policy should recognise the potential role that health providers, including pharmacists, can play in the medication management process, by using genomic testing and information to optimise outcomes for patients. Further, the use of pharmacogenomic

testing and technology should not be confined to MBS-funded service settings but should be utilised throughout the patient journey including in community pharmacies. Decisions on the funding of pharmacogenomic technology must be based on the Policy's principles of access and affordability for consumers.

Question 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:

- 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:

The Guild agrees with Pillar 4, and in particular supports the inclusion of the descriptor "responsive". The past few years have demonstrated the need for a sector that can quickly adapt to changed circumstances.

Being responsive also recognises the fast-paced nature of medicines, vaccines and medical devices development as well as changing consumer preferences and population health challenges. The draft Policy should discuss in greater detail the ways in which Australia's medicines regulatory, legislative, governance and accountability must prepare for the current and future developments in medicine-related therapeutics.

The past five years have seen prescribers, pharmacists and consumers faced with growing challenges from medications shortages and supply chain disruptions. These have worsened during the COVID-19 pandemic.

A secure, responsive and reliable medicines supply chain network is essential to the timely and equitable distribution of medicines throughout the country, and to addressing issues of equity and timeliness. A weak or vulnerable medicines supply chain is a national security risk.

The Guild proposes prioritising the following text by shifting it from the description to an intended outcome:

- Australia has a robust, responsive and reliable supply chain network that provides timely and equitable distribution of medicines throughout the country.

The Guild believes that Australia's network of nearly 6,000 community pharmacies deserve particular recognition in the Policy as the consumer-facing interface with Australia's medicine supply chain. The value that the pharmacy profession makes to health outcomes has never been more evident than in the past two years through its dedication to continuing provision of service, its flexible embracing of COVID-19 vaccination, acting as a partner to address supply-chain disruptions and pivoting to supply Rapid Antigen Test kits at short notice.

We believe the Policy should recognise Australia's community pharmacy network as the key point of contact for the provision of medicines and medicine-related advice to consumers. These should be backed by a commitment to support and expand the role of pharmacists to practice to their full scope of practice.

The Guild believes that the wholesale distribution network that underpins the supply of medicines to community pharmacy is of high strategic value to the health of the nation, without which we are unable to "meet current and future health challenges". We request that policy recognises the importance of support mechanisms, such as the Community Service Obligation for Pharmaceutical Wholesalers (CSO) as a critical component of a "responsive and sustainable medicines industry".

Section 6: 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.

Question 19: Implementation

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

- Disagree

You can explain your selection or provide comments below if you wish. (1000 words):

The Guild finds the implementation approach and supporting diagram to be simplistic and lacking in detail. Aspects of responsibility, governance and accountability are not discussed, nor is there mention of the success measures that will be used within a revised National Medicines Policy.

The examples provided in the Figure 3 do not recognise that substantial overlap exists between the "examples of mechanisms for integration" and the four Pillars of the Policy. Nearly all examples provided influence more than one of the four proposed Pillars of the Policy.

The Guild notes that the National Medicines Policy is a high-level document supported by secondary documents, programs and guidelines; however the absence of specific performance measures relating to the implementation of a revised National Medicines Policy is a matter of serious concern.

The Implementation section should recognise the responsibility of the Australian Government (as author) to communicate the existence and purpose of the Policy to consumers (individuals, carers, families and communities). Doing so will increase general awareness of the Policy and will increase the level of expectation and accountability for all partners to deliver on the Policy's principles.

Section 7: 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.

Question 20: Evaluation

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

- Disagree

You can explain your selection or provide comments below if you wish. (1000 words):

The Guild notes that the National Medicines Policy is a high-level document supported by secondary documents, programs, strategies, initiatives and guidelines; however the absence of specific performance measures relating to adherence to the aim, pillars and principles of the revised National Medicines Policy is a matter of serious concern.

We believe this section of the draft Policy requires substantial additional expansion to provide greater guidance for program designers. For instance, a phrase such as "each policy partner delivering actions aligned to the policy's pillars" is inadequate in describing the relative contributions expected from large, better resourced partners compared to smaller partners such as community-based health practitioners.

The draft Policy does not specify how the success of the National Medicines Policy will be measured, nor the mechanisms and time frames of review and future renewal.

Section 8: General Comments

Question 21: General Comments

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

The Guild supports in general the revised Draft Policy and the four Pillars identified. We have made recommendations for additional intended outcomes within our response. However, we find the draft policy lacking in specifics and detail in ways that we have already highlighted.

In addition, we make the following general comments:

- The Policy would benefit from being written in plain English, in line with the Australian Government guidelines¹, to be more accessible to all users of the policy, particularly consumers and those who care for them. This is critical to ensure a “person-centred” policy.

To provide but one example, the sentence, which occurs in 3 locations,

“In broad terms, the following partners have prime carriage of work to advance the achievement of this Pillar”

could be re-written as:

“The following partners are responsible for achieving this Pillar”.

- The Policy should recognise the importance of maintaining security of supply of medicines, medical devices and vaccines, as this is not recognised in the current Draft Policy. Australia’s vulnerability to medicine shortages has become evident over the past five years, but has reached the point of crisis throughout the COVID-19 pandemic.
- We note that the Enablers section mentions the need for the health workforce to work at their full scope of practice. We recommend that this be reiterated in other sections throughout the document, within each Pillar, to emphasise the need for this. Having health practitioners work to their full scope of practice will allow them to contribute to the healthcare system at an optimum level, in accordance with their acquired and assessed competencies, leading to improved health outcomes.²

¹ Australian Government, Style Manual, <https://www.stylemanual.gov.au/writing-and-designing-content/clear-language-and-writing-style/plain-language-and-word-choice>

² Pharmacy Guild of Australia, Scope of Practice of Community Pharmacists, https://www.guild.org.au/_data/assets/pdf_file/0023/106178/Scope-of-Practice-of-Community-Pharmacists.pdf