Consultation Draft- National Medicines Policy

Responses to Survey

2 March 2022

Q 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

The inclusion of an aim is a good addition; however, the lack of appropriate structures, processes and accountabilities make it unclear how the National Medicines Policy (NMP) will achieve its intended outcomes.

The inclusion of a vision, separate to the aim would improve the NMP. The vision could be aspirational and outline what the NMP is seeking to achieve to improve the health of all Australians in the context of our environment, culture and health system.

The inclusion of clear, time bound policy goals, or policy achievements, would further strengthen the NMP and support achievement of the Policy's aim. Such policy goals would provide further clarity around the actions and directions set by the NMP and assist all stakeholders to work toward achieving its aim in a constructive and collaborative manner.

The aim talks about structure, processes and accountability, which are appropriate. A vision would provide overarching policy context and show how medicines will improve the lives of Australians. Policy goals would support implementation and achievement of the aim.

Q 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.

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

Agree

It is pleasing to see the broad scope of the National Medicines Policy (NMP), and the definition of medicines expanded. It will be important to educate consumers, industry and health professionals about the changes to the definition of medicines in the NMP, and to alert stakeholders, including consumers, that products and medicines they use and/or prescribe may be now within the scope of the NMP. For example, people affected by cancer often do not include the use of some medicines in their medical history as they don't understand their relevance.

In implementing the NMP it will be important to differentiate between registered and conventional therapies and alternative, complementary or experimental therapies.

We support an agnostic approach to medicine and technology because it future proofs the NMP and assists it to stay relevant as research and development occurs. We are concerned however that in an effort to broaden the scope to ensure responsiveness there is a danger that the NMP could become stagnant or set and forgotten. It is important for the NMP to have a set timeframe (e.g. 2021 – 2031), with a clearly stated review cycle embedded within its framework, to ensure the timeline of the last NMP is not repeated.

Q 12

Principles The Policy includes key principles (person centred, equity, partnership based, accountability and transparency, innovation evidence based and sustainability), that should be evident in the planning, design and implementation of all policies, strategies, programs, and initiatives related to the Policy.

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

Strongly Agree to all principles

We are very supportive of the principles and particularly pleased to see the outcome of equity which is not simply focused on access.

It is pleasing to see innovation has been added as a principle, to enable processing and approval of innovative treatments, however we are concerned that the draft National Medicines Policy (NMP) does not adequately reflect its own principles. Highlighting how actions within the different Pillars of the Policy would be focusing on or underpinned by different Principles would enhance the influence of the Principles and ensure they remain a key focus for all stakeholders.

Q 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. They are health literacy, leadership d culture, Health workforce, research, data and information, technology and resources.

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

Agree to all enablers

We are pleased to see the inclusion of the enablers in the National Medicines Policy (NMP). We are interested in understanding how the enablers will be used to support the direction and implementation of the NMP, perhaps by guiding the governance structures of the Policy or underpinning its implementation plan, so that they do not become tokenistic inclusions. For example, in a sustainable health workforce, resources and research should not only be major enablers but must underpin the implementation of the NMP.

Q 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.

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

Neither agree nor disagree

It is pleasing to see a governance section included in the National Medicines Policy (NMP) however the current section does not provide adequate detail on what the governance structures will be nor how they will work. It is not possible to support the governance approach and structure when we do not know what they are.

The importance of the NMP as a high-level policy is clear, and we are pleased to see an extension to the roles and responsibilities of partners to include descriptions of circumstances including specifics in how to become an effective partner. However, the draft NMP does not detail the structures that will support partners working together to enact the Policy, nor what the consequences are (for both the partners and the NMP) if a partner is unable or unwilling to perform at the level required to meet the NMP's objectives.

The current draft NMP does not clarify relationships between partners nor demonstrate how overall governance involving all partners might work in a nationally coordinated way.

This section needs to include more concrete detail and the language needs to be stronger. For example, the NMP needs to state that committees and working groups *will be* established (rather than *may be* established) and outline how they will be funded and supported so the NMP can be direct in stipulating all partners will adhere to the outlined principles and monitor achievements against the Pillars. The NMP also needs to articulate how these expectations will be realised and what the consequences for partners not adhering to NMP principles and monitoring processes will be.

Measurement needs to be included in the governance of the NMP to make it clear how the Policy will achieve it's intended outcomes. The draft NMP could improve its description of governance by either having an overarching section that demonstrates how the aim of the NMP is measured against key performance indicators or policy achievements in all programs, or incorporate content in each section highlighting KPIs, targets/goals or policy achievements specific to each Pillar. Either of these strategies will add to the integrity of the NMP by providing high level guidance to programs and partners so it is clear how they show they are meeting the objectives of each Pillar, and by extension, the NMP.

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.

Q15

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

Due to the word limit we have responded to the Intended Outcome of Pillar 1 in Q 21

Description

While we are pleased to see that a specific focus on people living with rare diseases and under recognised conditions is included, the principle of equity is not well articulated in this Pillar. Although the inequitable health outcomes of Aboriginal and Torres Strait Islander people and Culturally and Linguistically Diverse communities are stated, the draft National Medicines Policy (NMP) does not go far enough to be clear that there are large populations of other underserved

people, such as LGBTIQ+ communities, people with a disability, people who are homeless, and low-income individuals and families. It is inadequate to group them under ''other population groups''.

The draft NMP does not recognise the role that the social determinants of health play in health outcomes and does not do enough to address the systemic factors within its remit that contribute to and drive inequality in our community.

The NMP has the opportunity to improve equity of medicine access. For example, in the Closing The Gap PBS co-payment program (CTG), patients cannot access CTG if the medicines are dispensed at public hospital pharmacies. The doctor is able to write the script in the public hospital however the patient needs to go to a community pharmacy to have the medicine dispensed under CTG. Many patients eligible for CTG have barriers to accessing their local pharmacy, such as institutional racism, transport, cost, and health issues meaning the intent of the program is not delivered due to systemic barriers.

People living rurally or in remote locations are visible in the description of the principle of equity however, like the acknowledgment that Aboriginal and Torres Strait Islander communities and Culturally and Linguistically Diverse communities, the particular circumstance that reduces the capacity of people living in rural and remote communities to gain timely, equitable and reliable access to needed medicines needs addressing in the NMP. Access to medicines requires access to health care and this remains a key challenge in delivering equitable health care in Australia, particularly for regional and remote communities. Geography needs to be added to the list of factors that impact health outcomes.

Out of pocket costs for medicines incurred by patients are usually higher as an outpatient than an inpatient in the public health system. It is unclear how institutions can apply programs of the NMP to fund medicines adequately to ensure patients receiving cancer treatment in the outpatient setting have the same access to medicines as patients receiving treatment in the inpatient setting. For example, patients often require outpatient access to medications to assist the safe, effective, and tolerable delivery anti-cancer therapy protocols. Often the latest evidenced-based, gold standard medicines attract a co-payment due to patent issues or re-purposing when accessed as an outpatient. This cost falls to the patient and adds to the financial toxicity of cancer.

When patients cannot afford out of pocket costs, the clinician can find themselves in the challenging circumstance of prescribing a less effective medicine that attracts full reimbursement to reduce the financial stress for patients and their families. This issue delivers a two-tiered health system, impacts equity and is not conducive to patient centred care.

When describing affordability and value-based care it is unclear how the settings of the draft NMP addresses cost barriers related to access to medicines or related services for individuals. It is important to consider how new structures can be implemented to accomplish this, such as the

UK's Cancer Drugs Fund, to support innovative medicines via a managed access arrangement while further evidence is collected to address clinical uncertainty.

Investment and disinvestment are discussed in this Pillar, however in our experience a comprehensive and systematic approach to disinvestment is rare, and disinvestment consideration is not routinely provided resources at the level and intensity required, other than with the introduction of genetics and biosimilars. The NMP and its implementation structures need to be built to facilitate disinvestment if it is a requirement of the NMP. The Policy needs to provide guidance by highlighting the need for resources to be identified to assist in the work of disinvestment and articulate the targets or governance structures that will provide oversight of this work.

Key responsible partners

When describing the roles and functions of the key responsible partners, the draft NMP focusses on the interdependence of partners, the need to respect expertise and a focus on a shared commitment to the Pillar. However, elevating all partners to having prime carriage of work to advance the achievement of the Pillar reduces the ability of the NMP to achieve its outcomes. How are all partners held accountable for their roles and functions and what measures are in place to ensure this is achieved? How is performance against the NMP to be measured? How do the governance structures of the NMP support its success? And how will this be funded?

As the NMP is a national policy and within the responsibility of the Commonwealth Government, the Commonwealth (through the Minister for Health and the Australian Department of Health) must be the overseeing and responsible party to which partners are accountable. Definitions and documentation of responsibility is required otherwise it is difficult to enforce accountability and maintain progress of the NMP. This sentiment is expressed in the Implementation section of the draft NMP however it needs to be clear under the roles and responsibilities in this Pillar that the Commonwealth Government has responsibility for governance of the NMP and implementing governance processes to ensure the intent of the NMP is realised. High level government commitment to and oversight of the NMP is crucial.

Q 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.

Strongly Agree

Intended outcome

Ensuring quality safety and efficacy is essential to an effective National Medicines Policy (NMP) and our national health system and workforce. It is important for the language to reflect the importance of this Pillar. Encouraging active participation by partners in identifying and

reporting issues is insufficient. Each partner must take an active role in meeting the standards of the NMP to clearly demonstrate the intention to commit to quality, safety and efficacy and this needs to be named in the Policy.

In its implementation, the NMP has a clear role in ensuring areas or situations where quality, safety and efficacy have been shown to be at risk are addressed. As such, to realise this Pillar the implementation plan must consider specific scenarios including the regulation of practitioner compounded complementary medicines, how care transitions are managed, digital access to health and medicine records and bridging the gap between hospital and community pharmacies to assist in the transition of care.

Key responsible partners

Building health literacy is important. The draft NMP currently names building health literacy as a responsibility of consumer organisations, individuals, families, and carers, which is correct and important. However, building health literacy must also be the responsibility of governments, regulatory agencies, educational organisations and health service providers and needs to be added as a function for these partners. It is unacceptable for health literacy to be only named as a responsibility for community.

Q 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.

Strongly Agree

Description

Person centred care – When describing the National Medicines Policy (NMP) partner efforts in ensuring health literacy, it is important to add information to the description of providing prompt appropriate, targeted and tailored support to individuals. Information is mentioned in other points, but it is more accurate to include it in this point as information and support are more effective if they go together, particularly where health literacy is concerned.

Key responsible partners

It is pleasing to see researchers – many who are practicing clinicians, allied health and related professionals – added into the draft NMP. However, researchers do not feature as a key responsible partner in this Pillar. Their important role in leading, managing and contributing to clinical trials and research in quality use of medicines and medicines safety needs to be articulated in this section, as many take a lead in in investigating or managing how medicines are used in practice and address new and emerging issues. Researchers also play an important role in cancer registries and provide advice to government committees and governance structures. It is

essential these functions are provided adequate support and funding to ensure appropriate research is conducted to enable the quality use of medicines.

Q 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

Intended outcome

It will be more specific if the title of this Pillar included Australia – that is, ''Responsive and sustainable Australian medicines industry and research sector''.

The pharmacology industry is a global business and Australia is a relatively small component and market for these businesses. We do not have the population and scale of other countries to encourage investment where our comparably small populations can benefit from specific and targeted medicines. The National Medicines Policy needs to support the growth and maintenance of the Australian medicines industry to increase its capability, research and development, manufacturing and leadership.

Key responsible partners

All governments have a responsibility to create a positive, stable and conducive business environment for clinical trials. Adding clinical trials as an example linked to research will assist in ensuring approval and access processes are addressed as part of national implementation of the NMP.

Q 19

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.

Neither agree nor disagree

It is pleasing the see the role of the Commonwealth articulated in this section, specifically that it will facilitate, co-ordinate and monitor the identification, engagement, and commitment of partners, but it is not clear how this will be achieved.

In our submission to the Review of the National Medicines Policy we called for the development of a transparent implementation plan with strategies which include facilitating stakeholder

partnerships and collaborations to support implementation and noted that the introduction of national legislation and regulatory frameworks will provide a structure to better support the updated National Medicines Policy (NMP). It is our expectation that such an implementation plan should include measures to support communication and the streamlining of processes to allow programs to align to the NMP and all stakeholders to effectively contribute to implementation. Such an implementation plan is not evident or referred to in the draft NMP. When the implementation plan is written it needs to show very clearly how it will hold all partners accountable for their role in ensuring the NMP achieves it intended outcomes.

Digital health initiatives and opportunities such as effective and appropriate telehealth services and frameworks, electronic medication and prescription management and monitoring, and digital access to health records (including imaging) will have an impact on the implementation of the NMP. The NMP implementation plan needs to ensure access to these services and records is available for patients and clinicians across all systems (regardless of public/private service boundaries or geographical borders), to ensure the quality and coordination of health care and the quality use of medicines. These initiatives will minimise deviations from optimal care and improve medicine safety during transitions of care.

Q 20

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.

Neither agree nor disagree

Success of the National Medicines Policy's (NMP) evaluation will be reliant on a plan that is time limited, with public goals, targets or policy achievements that are clearly stated and reported against. To be effectively evaluated, the NMP needs a timeframe, for example of 2022-2032, and a stated review cycle.

In the description under evaluation, the draft NMP states that Government structures may be established. A co-ordinated, national process with an appropriate management and governance structure, including specific committees and working groups, must be established to ensure relevant polices, strategies and programs align to the NMP. Including significant numbers of consumer representatives in these groups and building consumer consultation processes as part of the evaluation plan, will elevate the visibility and relevance of the NMP and aid in the implementation of the Policy. Appropriate medical and allied health representation across the public and private health sectors and a diversity of disciplines and specialities is also required.

The NMP is a high-level policy framework and is not meant to be prescriptive about program delivery, however, it is not currently clear how the Policy will outline how its intended outcomes will be achieved. There needs to be a clear line between key performance indicators of the programs supporting medicines in Australia and the intention of the NMP. The evaluation section

of the draft NMP currently lacks clear targets, goals or actions to support activity and inform evaluation.

Q 21

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

There is an overwhelming theme in the National Medicines Policy (NMP) consultation draft of a lack of accountability and responsibility in describing exactly which stakeholders and partners are doing what, how and when. It is a high-level policy document, however it is not granular enough to hold professions, institutions, and policy makers to account to deliver the "patient-centred" care it is trying to achieve.

The NMP must have:
1. A clearly articulated timeline (e.g. 2022-2032) and a stipulated review cycle (e.g. 5 yearly)
2. A time limited evaluation plan with clear public reporting of goals/targets and policy achievements
3. Governance responsibility clearly identified as sitting with the Commonwealth
4. A major focus on developing solutions which enable people with specific conditions (e.g., cancer) to access safe and effective registered products which can be considered for subsidy. Specifically, the repurposing of prescription medicines in oncology which is also likely applicable to other therapeutic areas.
5. Funding for implementation.

The TGA has appropriately and recently identified key issues relating to repurposing prescription medicines, demonstrating a good understanding of both the issues and opportunities to enable better patient access to clinically appropriate medicines. A focus on this work should be reflected in both the NMP and its implementation plan. In our view, the most critical and challenging areas are the lack of commercial incentive for a sponsor to register a new indication; and the ability to access the required evidence when a sponsor does not want to register a new indication. A potential option to address the issue is to actively pursue registration and potential PBAC review of additional indications for medicines. This allows industry and other organisations such as clinical or patient groups to apply and for the TGA to play an active, rather than passive, role in enabling Australian's access to safe and effective medicines.

The key components to include in a working repurposing concept are:

- The sponsor remains responsible for post-market requirements including pharmacovigilance as non-commercial organisations are not likely to have the financial resources or necessary expertise and infrastructure.
- Establish a requirement that the applicant would submit to the PBAC for consideration for listing on the PBS.
- Sponsor of the medicines original purpose must be obliged to provide evidence for the extension of the indication.
- Fee relief assessment based on pre-determined criteria.

Considerations and elements in the feasibility and impact of these changes need to be considered including:

- TGA resourcing and capacity, including the need to cost recover these activities.
- Feasibility of non-commercial organisations to raise applications and meet the ongoing responsibilities of sponsorship if approved.
- Accessibility of evidence and data to support the extension of indications by non- commercial organisations.
- Legal elements and potential barriers for non-commercial organisation applications, including whether commercial companies could block submissions, and ongoing pharmacovigilance arrangements.
- Legislative changes to enable flexible options without compromising on consumer safety.
- Consideration of unintended consequences such as bias or conflicts of interest, disruptions to access of other generic medicines if exclusivity is provided to one brand, and impact on PBAC processes and protocols.
- The feasibility of incentives, including the real impact these incentives have on achieving the desired outcome are also required.

Response to the Intended Outcome of Pillar 1

We are pleased it is articulated that the National Medicines Policy (NMP) is seeking to ensure Australian communities have timely, equitable and reliable access to safe and affordable medicines, particularly as there is an issue of equity of access to medicines with many Australians experiencing financial toxicity due to cost of treatment. Pillar 1 is laudable but requires substantial systemic change to the national prescription and therapeutics regulatory approval system to address longstanding anomalies and barriers in the provision of timely and cost-effective access to medicines, if it is to stand as an effective element of the NMP framework. Such systemic change needs to be considered and addressed in the NMP's implementation.

Costs associated with cancer treatment affect all people affected by cancer as well as the institutions providing care. This Pillar needs to consider the different sources of the cost of medicines and the different solutions implemented to address cost barries. As an example, compassionate programs are part of the solution however they are not without hidden costs for both the patient and the health system (e.g. consultation fees, pharmacy resources, staffing and components required for drug administration). These are costs that can be considered in the implementation of the NMP.

This Pillar needs to identify that medicines will improve and maintain health and wellbeing as both elements are important to health outcomes.

The parameters of timely access are not clearly defined. It makes sense that each program underpinned by the NMP will be specific regarding how timely access relates to the issues they

are focussed on. However, the draft NMP would benefit from the inclusion of a statement that articulates that expectation –each program requires key performance indicators to demonstrate how it delivers against the principle of this Pillar. As this suggestion relates to all four Pillars in the NMP, it may be more efficient to have an overarching section addressing the link between program delivery and the NMP.