CJA/GHLFA submission for NMP review

Terms of Reference 1: Evaluate the current NMP objectives and determine whether these should be modified or additional objectives included. This includes consideration of the proposed Principles to be included within the NMP.

Proposed Principles:

• Equity – all Australians receive effective, safe, high-quality, and affordable access to medicines when needed irrespective of background or personal circumstance.

• Consumer centred approach – consumers should be informed, engaged, and empowered to participate in medicines policy, recognising their key role in supporting the achievement of the policy's objectives.

• Partnership based – establish and maintain active, respectful, collaborative, and transparent partnerships, to harness stakeholders' skills, experience, and knowledge.

• Accountability and transparency – all stakeholders are identified and accountable for their responsibilities and actions towards delivering or contributing to the achievement of the policy's objectives, within a transparent framework.

• Stewardship – all stakeholders have a shared responsibility to ensure that the policy's objectives are met in an equitable, efficient, and sustainable manner, as stewards of the health system.

Q1a. Are these proposed principles appropriate? With regard to the proposed principles, is anything missing or needing to change?

These comments are submitted by Global Healthy Living Foundation Australia (GHLF Australia) on behalf of its CreakyJoints Australia patient community. .

We believe the proposed principles are appropriate and closely reflect our CreakyJoints Australia *Patient Charter* which states:

- Our experience is at the heart of medicine; thus, we must be at the centre of all medical decision making.
- We must play an active role in our own health, including decisions we make about food, exercise and other lifestyle choices.
- We can empower ourselves and others to make our voices heard if we are provided with the right education and tools.
- Care providers should inform us of all relevant treatment options, including non-medical ones to help us achieve the best health outcomes.
- Access to care should not be limited.
- We have the right to a second opinion.
- Elected officials, drug manufacturers and all associated healthcare professionals must make it their goal to ensure patients are central to all decisions.

- We must be treated with dignity, transparency and respect by everyone involved in the healthcare process.

Additional comments from our community

"Equity: Equitable access to medicines for those who do not have equitable access to doctors, because they cannot attend consults, e.g. due to locality, being in disability or aged residential care, being homebound.

Stewardship: Given that use of medicines in Australia is evidence based, stakeholders should include researchers and research funders for both clinical trials and translational research."

Penelope McMillan

NMP's four central objectives:

• timely access to the medicines that Australians need, at a cost that individuals and the community can afford;

• medicines meeting appropriate standards of quality, safety and efficacy;

• quality use of medicines; and

• maintaining a responsible and viable medicines industry

Q1b. Are these four objectives still relevant? Should any be modified, or any additional objectives be considered? If so, how and why?

The central objectives are still relevant. As the NMP review, the House of Representatives enquiry and the strategic agreement between Medicines Australia and the Federal Government progress, we would like to see particular attention paid to improving processes related to:

Access

- Increased access to in-home medical services for people with limited mobility or practical means to attend services outside of their home.
- Changes to the current regulations regarding access to biologic (and other innovative) medications to allow for advancements in research that result in more advanced products available to patients..
    - Example 1: People with rheumatoid arthritis can currently only "fail" five biologic medications in their lifetime whereas people with other forms of autoimmune arthritis who have failed several biologics can wait several years then restart the application process. Australian patients jump through hoops that result in additional access restrictions.
    - Example 2: people with many chronic diseases cannot readily access medications approved by TGA but not yet listed by PBAC. This delay in access to approved treatments disadvantages Australian patients, especially when compared to patients in other developed nations, who benefit from innovative therapies much sooner.

- Changes to the current regulations regarding access to opioid medications to better cater for people with chronic health conditions who have been using such medications responsibly and under their doctor's supervision for many years — especially those for whom other forms of pain management have not worked or are not appropriate.
- Improved communication directly to consumers regarding access to medications in emergencies, such as fires and floods, or when there are medicine shortages.

Quality use of medication

We support the need to review and update three national Quality Use of Medication publications related to the NMP.

As a non-profit patient-centered organisation, our mission is to improve the quality of life for people with chronic illness. One way we achieve this is to share reliable information about relevant medicinal and non-medicinal treatments for the conditions we support. We rely on information from Australian governments, reputable organisations and healthcare providers to provide this information that we then communicate via accessible formats and in "plain language". Therefore we would like to see the focus on this area is not only maintained but regularly reviewed and improved.

Maintaining a responsible and viable medicines industry

The current global shortage of tocilizumab has affected many members of our patient community with autoimmune arthritis. Therefore, we support the need for high level considerations within the NMP review to help offset and/or prevent such occurrences.

As we noted above, we also believe it is critical that more attention is paid to communicating timely information directly to affected consumers along with advice on how they can manage their condition when they cannot access their usual medication. Enabling direct communication, where appropriate, between manufacturer and patient would improve emergency response effectiveness.

Additional comments from our community

"If I had to say anything though that encompasses the direction I think the NMP needs to head, I think that we need to move toward a 'national Access to care/treatment policy', which will cover everything from diagnostics, to preventatives, to treatments (whether a service, device or medicine)."

Janelle Bowden

"Access to medicines: The PBS is inadequate for people living in poverty who cannot afford over the counter medicines and nutritional supplements, even though they may be part of a management plan for chronic illness.

Access to medicines through public hospitals is not equitable for those who do not have easy access to public hospitals.

Quality use of medicines: Best practice is only possible when there is an evidence base. Therefore: There should be a research feedback loop, from significant non-PBS use of medication into funding clinical trials: medications which are either off-label use; non-PBS cohorts; not on the PBS at all.

QUM partners should include researchers and research funders, including the Australian health translation centres, the NHMRC and the MRFF."

Penelope McMillan

Terms of Reference 2: Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies.

Q2a. Should the current NMP definition of medicines be expanded to include medical devices and vaccines? Why or why not? How would a change in definition of medicines be reflected in the policy's high-level framework?

We believe there is a need for policies related to medical devices and vaccines to be considered and updated within the range of reviews that are currently occurring in the health system.

Ideally, it would help for the definition of medicines to be expanded to include both medical devices and vaccinations as this would ensure consistent communication and planning.

We believe that **vaccines** should be included in the definition of medicines for several reasons:

- Vaccines are critical to the maintenance of Australia's strategy against preventable disease and are increasingly and rightfully being used as a form of preventative treatment.
- Vaccines are often administered by GPs and pharmacists, the same people consumers rely on for information about medicines. This is an important pathway for sharing information with consumers and gathering feedback from consumers to share with policy-makers.
- Vaccinations sometimes require patients to change the timing or dosage of their regular medications so this type of communication needs to be consistent and clear. For example many immunosuppressed people had trouble accessing appropriate or detailed information about the timing of their medication in the months following the COVID-19 vaccination rollout. This subject was discussed amongst rheumatologists but the information they shared with their patients was inconsistent and, sometimes, non-existent. This left consumers searching for information and unnecessarily impacted on the confidence of some.
- Vaccines protect the whole community. The profile of vaccination has suffered in recent years witnessed by adults being under vaccinated. Until vaccines and vaccination are given greater consideration and profile, complacency and hesitancy may impact on levels of coverage. Globally, vaccination coverage reduced by 3 per cent, WHO reported in early 2020. If coverage in Australia is to remain high, vaccines and vaccination must be given higher priority.

If the definition is not expanded to include **medical devices**, existing policy frameworks related to medical devices would need to be regularly updated to complement the NPA. All related policies would also need to be cross-referenced so that people do not need to go searching for policies related to things like biologic medications and the devices used to administer them, for example.

Another example of an overlapping area would be the mixed-messaging related to the use of medical gloves when self-administering subcutaneous methotrexate for autoimmune conditions.

Q2b. Does the policy's current title, the "National Medicines Policy", reflect the breadth of health technology developments within the policy's scope? If not, how best can these and future health technologies be better represented in the policy's title?

If the definition of "medicines" is not expanded to include vaccines and medical devices, then the existing name is fine.

However, if the definition is expanded, the policy title should change to reflect this. For example, if it expanded to include vaccines but not medical devices, the title could simply be the National Medicines and Vaccines Policy.

If the definition is expanded to include both, the title could be the National Healthcare Products Policy.

Equally, prevention or preventative could be considered in the title National Medicines and Preventive Therapies Policy. The term "medicines" often implies the cure and not the role it plays in prevention or maintenance of health.

Additional comments from our community

"What about nutritional supplements, complementary medicines and over the counter medicines, that are part of an illness management plan, but which those living in poverty cannot afford? This is one element of socially determined poor health outcomes.

Medical devices and vaccines ought to be under the NMP, however this will require bringing Medicare into the stakeholders and scope of the Policy."

Penelope McMillan

Terms of Reference 3. Assess the NMP's utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.

Q3a. How has the NMP been able to maintain its relevance and respond to the changes in the health landscape?

The ability for the NMP to respond to these changes has been patchy. During the COVID-19 pandemic, rapid changes in digital health technologies have been welcome. However, before the pandemic, technologies such as telehealth and apps to record patient-reported outcomes and real world evidence were underutilised, under-resourced or negatively affected by excessive red-tape.

Also, the speed of development, approval and introduction of new treatments over the last few decades has not been effectively matched by access, reimbursement, regulations and in some circumstances, supply, putting Australian patients far behind other countries throughout Europe, North America and Asia from an overall access standpoint. Australian patients deserve to have access to the same medicines as American or Canadian patients do, and updated reimbursement schemes should address this.

Q3b. How could the NMP be refreshed so that the policy framework is able to better address current and future changes in the health landscape? What is missing and what needs to be added to the policy framework, and why?

We believe that the discussion paper covers the numerous areas that need to be considered for change very well.

It is vital that the revised NMP be used to inform all the other associated health reviews and reforms currently taking place to ensure consistency and minimal duplication.

What appears to be missing is a visual representation, such as a flow chart, of how these reviews interact and overlap. Such a chart should be in plain language and downloadable from all relevant websites.

Additional comments from our community

"Health literacy: It is crucial that access and inclusion strategies are applied for people with a disability, so that they have access to health information that is appropriate and enables better management of health. People with a disability were left off the list of marginalised groups with poor health.

Financial and geographic barriers are not the only problems with accessing new treatments options. People with disabilities need support to implement new treatment plans. (Note that NDIS only serves a portion of people with disabilities and is disproportionately not accessed by those least able to negotiate bureaucracy and follow complex instructions.)"

Penelope McMillan

Terms of Reference 4: Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers' needs and expectations.

Q4a. How can the NMP's focus on consumer centricity and engagement be strengthened? Is anything missing, and what needs to change?

We believe that, while the current NMP does not adequately include the needs and expectations of consumers, the points outlined in the discussion paper show us that there is a strong recognition of the need for change in this area.

As we mentioned in our response to ToR1, CreakyJoints Australia and our parent organisation, Global Healthy Living Foundation Australia, put the consumer at the centre of everything we do.

Areas that we believe need particular attention include:

- Improving access to treatment and care across all areas of health, especially for disabled and otherwise disadvantaged people. The delay in getting all people who were in Phases 1a and 1b vaccinated for COVID-19 was an example of a major and concerning gap in the system.

- Improving communication with people who are not computer literate or who cannot easily access the internet.
- Providing more opportunities for consumers to share patient reported outcomes and real word evidence through research. For example, collecting more data like this from participants of clinical trials and from people using apps to monitor and treat their conditions.
- Allowing and providing opportunities for direct two-way communication between pharmaceutical companies and consumers in appropriate circumstances.

Reaching diverse consumers beyond those in the front line requires comprehensive communication to engage target populations. Without a commitment to communication and incentive to engage, there will continue to be limited participation.

Additional comments from our community

"Speaking as a patient with a long term chronic inflammatory musculoskeletal condition, over the past 50 years I have been prescribed many medications and received a plethora of treatments and procedures. In all cases, there was very little opportunity to make informed decisions from the available information.

This review provides an opportunity to support patients with medical information at all levels and utilise new electronic platforms available to deliver to all members of our communities."

Annie McPherson. President Ankylosing Spondylitis Victoria Inc.

"Disability access and inclusion is missing from the list of ways to achieve individual and community health literacy.

Consumers seem to be considered here as a generic group. There needs to be recognition of the diversity of consumers, the diversity of consumer roles, and the importance of engaging with those specific consumers who will be directly affected by a particular decision."

Penelope McMillan

Terms of Reference 5: Identify options to improve the NMP's governance; communications, implementation (including enablers) and evaluation.

Q5a. What opportunities are there to strengthen governance arrangements for the NMP? What would these be, and why?

Q5b. How can communication about the NMP be enhanced or improved?

Q5c. What would be effective mechanisms to support communication about the policy?

To support community contributions the policy requires accessible education content, comprehensive health promotion and community delivery in trusted settings. Additionally, broader community health

communications delivered in major media and social platforms is required to encourage participation. With more than 50 per cent of the population living with a chronic condition, a broad and targeted communication strategy is needed.

Additional comments from our community

"It would be helpful to have a readily identified central source for information, including ongoing information and announcements. This should include a website and social media accounts clearly linked to the website."

Penelope McMillan

Terms of Reference 6: Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.

Q6a. How should the NMP's 'partnership-based' approach be defined?

Q6b. What is missing from the policy's reference to the NMP partners? Are there other partners that should be included in the policy? Who would they be and why?

Q6c. How could the NMP be refreshed to support greater accountability amongst the NMP partners? How could the partnership approach be improved?

Q6d. How are conflicts of interest currently managed and should more be done to address this amongst the NMP partners? What approaches could be taken?

While we recognise the areas outlined in the discussion paper need to be addressed, we have no suggestions to share at this time.

Additional comments from our community

"Groups with responsibility for advancing the policy objectives should include researchers and research funders, particularly in clinical and translational research."

Penelope McMillan