



Consumers Health
Forum OF Australia

Submission to the Review of the National Medicines Policy

October 2021

Consumers Health Forum of Australia (2021)
*Submission to Review of the National Medicines
Policy Canberra, Australia*

P: 02 6273 5444

E: info@chf.org.au

twitter.com/CHFofAustralia

facebook.com/CHFofAustralia

Office Address

7B/17 Napier Close

Deakin ACT 2600

Postal Address

PO Box 73

Deakin West ACT 2600

*Consumers Health Forum of Australia is funded
by the Australian Government as the peak
healthcare consumer organisation under the
Health Peak and Advisory Bodies Program*

CONTENTS

Contents

Executive Summary	4
Background	5
About CHF	5
Recommendations	7
Terms of Reference	8
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	8
2. Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies	13
3. Assess the NMP's utility in the context of rapidly evolving treatments options, population changes, interconnected relationships and system-wide capacities	13
4. Consider the centrality of the consumer within the NMP and whether it captures the diversity of consumers, and their needs and expectations	19
5. Identify options to improve the NMP's governance; communications, implementation (including enablers) and evaluation	21
6. Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest	22
Conclusion	24

Executive Summary

The Consumers Health Forum welcomes the review of the National Medicines Policy.

The medicines environment has changed greatly over the past two decades. More targeted health deliveries bringing more complexity to the Quality Use of Medicines (QUM) environment mean we must take a multi-pronged approach in improving the NMP while always keeping the consumer front and centre of the policy, as those who will most benefit from it.

The following summary incorporates feedback from health consumers who are members of CHF's special interest groups. They confirm the need for inclusivity, diversity, collaboration, and equity. Key suggestions for improving and ensuring a refreshed strategy is more contemporary include:

- Strengthening principles around plain English language use, including writing the NMP in such a way that the consumer is at the centre of all aspects, aims and goals of the policy and that all elements must relate back to the benefits for consumers
- Consumer centricity must be strengthened through principles that involve a diverse range of consumers in shaping the policy, its implementation and its oversight
- There needs to be much greater focus on governance, oversight of, and transparency around, priority setting for implementation of the NMP. This includes having an annual forum resulting in regularly published performance report cards
- Needing to strengthen principles around investing in researchers and research
- Include a principle and stronger commitments to action to promote health literacy and consumer education around safe and quality use of medicines as well as the functions of key programs such as the PBS
- Acknowledgement of other major areas of reform such as digital and primary health care, particularly mention of the need for models of care that promote QUM e.g. general practice-based pharmacists
- An updated definition of 'medicine' to include any product that acts as a medicine, which focuses on therapeutic effect rather than its form
- A central focus on an outcome orientation, and commitments to the measurement of its impact and how it will be judged in terms of its impact on the health outcomes of Australians
- How the policy delivers on equity and equality and is inclusive of diversity must be clear. The policy itself should be universal but should provide scope for flexible application to meet differing needs of diverse groups of consumers. It would be helpful for consumers and stakeholders alike that there be a multi-layered digital map, showing the overarching policy, the many stakeholders, and organisations beneath that policy; how other policies are influenced by the NMP; how the policy is enacted and affects the lives of consumers through, for example, the Pharmaceutical Benefits Advisory Committee (PBAC), the Pharmaceutical Benefits Scheme (PBS) and through QUM etc. Within that map, the scope, and responsibilities, including Key Performance Indicators (KPIs) must be laid out.
- There needs to be a robust implementation and communication plan which focuses on consumers so they know the Policy exists and what it means for them.

Background

The National Medicines Policy (NMP) has guided the quality use of medicines (QUM) in Australia since its inception in 1999. Developed by the Australian Pharmaceutical Advisory Council, the policy aims to improve positive health outcomes for all Australians through their access to, and wise use of, medicines. The basic principles are about using the right medicines in the right doses at the right times to achieve quality health outcomes for consumers.

Since the publication of Australia's first NMP nearly 22 years ago there have been significant advances in technology and pharmaceuticals, more personalised medicine, and more targeted health deliveries.¹ This has brought with it more complexity. Greater costs, and greater expectations around quality health care mean substantial challenges in maintaining a viable and responsible medicines industry. It also means needing to restrict the use of some medicines to address challenges like antimicrobial resistance, which the World Health Organisation has stated as being one of the top 10 global public health threats facing humanity, driven largely by the misuse and overuse of antimicrobials and antibiotics, leading to the development of drug-resistant pathogens.²

There have been major changes in consumers' and health workers' expectations; changes to the health care system itself; changes in medicines and medicine delivery, health costs and remuneration; advances in digital technology, health literacy and communications, and changes in the pharmaceutical industry. The settings in which prescribers and dispensers operate have also changed, including some of the agencies that work to support them. For example, we've seen the advent of NPS MedicineWise, and divisions of general practice evolve to Primary Health Networks (PHNs). All these changes challenge as well as create opportunities for the underpinnings of the NMP and its implementation.

Changes and advances for consumers means that the whole web of systems, policies, guidelines, and legislation, all need updating and re-thinking with the understanding of how people are currently needing, accessing, and using healthcare, and how that is likely to continue changing in the future and that before costs and resourcing is considered.

About CHF

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

- advocating for appropriate and equitable healthcare
- undertaking consumer-based research and developing a strong consumer knowledge base
- identifying key issues in safety and quality of health services for consumers

¹ Bilkey, G.A., Burns, B.L., Coles, E.P., Mahede, T., Baynam, G. and Nowak, K.J., 2019. Optimizing precision medicine for public health. *Frontiers in public health*, 7, p.42.

² World Health Organization, October 2020. Antimicrobial Resistance. World Health Organization fact sheets. <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance> accessed 23 March 2021.

- raising the health literacy of consumers, health professionals and stakeholders
- providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making.

CHF member organisations reach thousands of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is bringing consumer expertise, perspectives, and ideas to the policy discussion as “patients are the only ones who have a systemic view of health”.³ Medicines and medicine safety are key issues for healthcare consumers and CHF has been an active participant in many medicines related policy initiatives. We were advocates for the current NMP, we and consumer representatives nominated by us are active participants in the work of the Pharmaceutical Benefits Advisory Committee (PBAC), the Therapeutic Goods Administration (TGA) and the stakeholder governance of the 7th Community Pharmacy Agreement. We have a Working Together Agreement and a contract for services as the consumer Quality Use of Medicines (QUM) steward for NPS MedicineWise, and we have been active in partnering with clinical collaborators such as the Pharmaceutical Society of Australia (PSA) to advocate for the safety and quality use of medicines to be a National Health Priority Area (NHPA).

To inform our submission CHF has held discussions and consultations with consumers. Before the discussion paper was released, we consulted our Safety and Quality Special Interest Group on the general principles for a refreshed NMP and then again on the proposed terms of reference

We have held two separate consumer-oriented consultations. The first was a webinar with open registrations and the second was a closed consultation with CHF members and other consumers. We also participated in the Medicines Australia webinar for patient organisations and the Making Connections Symposium and collected many consumer insights from those processes which augmented our own process.

There were differing views on many elements of this review, given the diversity of consumers involved across these processes. There were some strong common themes which we have focused on in our submission while still noting where there were divergent views and the need to take into these into account.

CHF always takes an evidence-based approach to our policy and advocacy. For this submission we looked at some of our own research and well as looking the broader literature on what is important to consumers about medicines and medicines policy.^{4,5}

One of the barriers to introducing more active care models has been the belief among some clinicians and policy makers that consumers are not interested in their own health care. The CHF *Patient Activation in Australians with Chronic Illness*⁶ survey dispels this view, finding that consumers are interested and want to take responsibility for self-management and be

³ Dumez, V., 2021. Why is it time to reimagine health and social care? Shifting Gears Summit, Opening Plenary.

⁴ Australian Department of Health, 2021. *Consumer Health Literacy Segmentation Research*. Consumers Health Forum of Australia.

⁵ Consumers Health Forum of Australia, 2021. *Supporting Primary Health Networks to build health literacy to improve the quality use of medicines in their communities* (unpublished)

⁶ Consumers Health Forum of Australia, 2019. *Patient Activation in Australians with Chronic Illness*.

involved in shared decision-making. CHF's current and as-yet unpublished research—*Supporting Primary Health Networks to build health literacy to improve the quality use of medicines in their communities*—aligns with the *Consumer Health Literacy Segmentation Research* in identifying three levels needed to develop a practical national health literacy framework, in line with the recommendations in the draft National Preventive Health Strategy. This included a policy-level framework; instigating a culture change in primary care by developing ways and means for communications and general practice to include more of a focus on health literacy as it relates to QUM, and practical tools as a part of that strategy, to increase and improve health literacy and health literacy as it relates to QUM.

Recommendations

What consumers need to know and see is how the policy is working for them and CHF makes the following key recommendations to ensure that the new National Medicines Policy delivers that objective.

One issue which we have not tested with our consumers but is worth considering is whether the Policy would be better described as a framework within which all medicines related policies, programs and initiatives sit.

We have divided our recommendations into three groups; the content; the presentation; and implementation issues.

What the Policy should say

- The policy must have an overarching statement of intent that its purpose is to confer significant benefits, and is relevant to, all Australians.
- The NMP needs to be written in such a way that the consumer is at the centre of all aspects, aims and goals of the policy and that all elements must relate back to the benefits for consumers. Consumer-centricity should be one of the core principles of the NMP
- The suggested principles should be included. An additional principle of timely access to medicines and a focus on outcomes must be considered as stand-alone principles.
- The objectives as suggested should be in the Policy with a fifth objective relating to a viable medicine research capacity and support for clinical trials
- The policy must include medicine research and researchers as stakeholders
- The scope of the policy should be broadened to include medicines and medical devices that are integral to the delivery of those medicines. Consideration be given to having a companion policy on medical devices

How the Policy should be presented

- The policy should be written in plain English with a glossary of terms and/or be accompanied by a consumer and community explainer. The policy needs to find a careful balance between a high-level policy and the inclusion of language that can be understood by consumers who are the key beneficiaries of the NMP
- Consumers and stakeholders need to see a clear map of the multi-layered relationships, partnerships, programs and other architecture that operate under the NMP. This should be in the form of a digital map showing the overarching policy, the many stakeholders, and organisations beneath that policy; how other policies are influenced by the NMP; how the policy is enacted and affects the lives of consumers

through, for example, the Pharmaceutical Benefits Advisory Committee (PBAC), the Pharmaceutical Benefits Scheme (PBS) and through QUM etc.

- Within that map, the scope, roles and responsibilities of the various parties and Key Performance Indicators must be laid out.

How the Policy should be Implemented and measured

- A central focus of the NMP must be the evaluation and measurement of its impact and how it will be judged in terms of its impact on the health outcomes of Australians
- There should be a high-level implementation oversight and review governing committee with consumer involvement. Consumer involvement should include more than one voice
- There should be an annual National Medicines Policy Forum, open to anyone who wishes to attend. This should include a mechanism for consumers to ask key stakeholders, including the Department of Health, questions about the implementation and impact of the NMP. The design of this Forum should be co-designed with consumers and the commitment to it should be in the policy
- There should be a regular published report card of performance (e.g. annual)
- There needs to be a commitment to a 5-year review which focuses on impact.
- How the policy delivers on equity and equality and is inclusive of diversity must be clear. Consumer feedback was unanimous that the policy itself should be universal but should provide scope for flexible application to meet differing needs of diverse groups of consumers
- There must be significant consumer consultation on the draft policy with evidence of that consultation covering a broad group of consumers covering the diversity that exists.
- There needs to be a consumer-focused communication strategy supporting the release of the new policy to ensure consumers know of its existence.

Terms of Reference

The following responses keep the primacy of the consumer at the centre of the NMP in considering the terms of reference for this review.

- 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.***

The following principles have been proposed for inclusion in the refreshed NMP:

- **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.

Question: 1A

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

CHF agrees that the five principles are appropriate. Below are some comments on each of the five and how they might be enhanced.

There needs to be a closer link between the principles and the objectives, using the same language and showing how they relate to each other.

The principles would be improved by being presented as a short phrase in a headline-like fashion and/or include a short paragraph of explanation to demonstrate that principle in action in terms of medicines and medicine policy.

The current principles do not adequately address the issue of innovation: the need to encourage and drive it and ensure the policy is responsive to change at all levels. It does not easily fit into the current principles and so there needs to be an additional one.

Equity

There was consensus among consumers CHF consulted that equity must be a key principle and that, overall, the general statement about equity is sufficient. There was a great deal of discussion during the CHF consumer consultation about the lack of diversity within the health consumer space. The descriptor under the 'equity' heading should include mention of the lack of diversity in the health, health consumer, and medicines spaces which must be addressed. It would not diminish the description of equity in medicines for diversity to be added as part of its aim.

Equity

Equity: All Australians receive the most effective, safe, high-quality, appropriate and affordable access to medicines when needed irrespective of background or personal circumstance. Robust measures are in place to minimise barriers to access particularly around cost.

Consumer centred approach

Rather than including consumer-centricity as one of the principles it should be an overarching focus of the entire policy. The language used in the descriptor does not reflect that centrality. The overwhelming response regarding the consumer-centred approach is that most health consumers are not empowered when it comes to taking part in the health system. The principle needs to acknowledge that this is not easy to do

“Engaging and empowering consumers does not happen easily. There needs to be opportunity to ask questions and to engage for consumers to become informed.”

CHF suggests the following wording:

Consumer centred approach: consumers are involved at all levels of the policy, contributing to its development, implementation and evaluation. They will be provided with information and opportunities to be involved and feel empowered to initiate discussion about the direction and implementation of the policy given its key objective is to improve health outcomes for consumers.

Partnership

While this principle is supported the descriptor is not clear and the following is offered as an alternative:

Partnership based: all stakeholders commit to working to ensure that active, respectful, collaborative, and transparent partnerships are in place to effectively deliver the policy in line with its objectives. These partnerships include consumers, health practitioners' health and aged-care facilities, medicines industries, medicines researchers, media, funders and Commonwealth, state, territory, and local governments.

We have listed the key partners to clarify the breadth of the policy. This is in line with our recommendation that the principles should have a more of a description than they are currently given.

Accountability and transparency

CHF supports the notions of accountability and transparency and that it applies to all the stakeholders. Some consumers have some concerns with the wording for this principle as it has the potential for shifting responsibility from other stakeholders, notably governments to consumers. They expressed some concern that this principle could be seen to undermine the right to health and would be detrimental for the many groups in the community that are marginalised when it comes to health and medicines. They raised concerns that the consumer cannot be held accountable nor responsible when “the system needs to allow consumers be part of it”. When a person is unwell, they do not have the capacity to engage in a process, nor be accountable or responsible for that process or that system.

CHF would like the principle to be more focused on providing accountability and transparency to consumers as users of the system and the funders of it, through taxation and personal incomes.

Alternative wording is suggested below:

Accountability and transparency: all stakeholders are accountable for their responsibilities and actions as identified with the policy. They all commit sharing information about their contributions in a transparent process that is visible to all other stakeholders.

Stewardship

Whilst this principle is endorsed it was seen by many consumers as “not as important as the others”. There was an acknowledgement that stewardship is “a shared responsibility”. There was much discussion, however, focusing on appropriate language use pertaining to the embedding of consumers at all levels of this policy. In some ways this poses the same problems identified in the accountability and transparency principle above.

The term 'stewardship' means nothing to grassroots consumers. There was acknowledgement that those providing feedback understood the term to mean "everyone is responsible to looking after the process" and understood its meaning regarding this policy. To overcome this CHF suggests stewardship could be replaced by "responsibility" or "ownership" which are more broadly understood a more broadly recognised word than "stewardship", and "ownership". Both were thought to be more appropriate.

Alternatively, the descriptor could be rewritten slightly as below:

Stewardship: all stakeholders are joint owners and so have a shared responsibility, within their means and capacity to ensure that the policy's objectives are met in an equitable, efficient, and sustainable manner, as owners and users of the health system.

Timeliness

CHF is suggesting an additional principle around timeliness of access. Whilst this is implied in the equity principle it is an issue of great importance to consumers and it should be a separate one.

CHF believes there needs to be a more direct reference to timeliness of access with an identified principle addressing that as the best approach. It is in the objectives but for many consumers it needs to be elevated as a principle as it is seen as one of the main barriers to effective access to appropriate medicines. This is particularly true for people with life threatening illnesses and others where timely access improves quality of life and impacts on the longer-term progression or otherwise of the disease.

Timeliness: All Australians have access to medicines when they need them and the processes for regulation and reimbursement are designed to achieve this.

Question: 1B

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

The original four pillars on which the national medicines policy sits are:

- timely access to medicines that are affordable to individuals and the community
- high-quality medicines that are safe and effective
- the quality use of medicines
- maintenance of a viable and responsible medicines industry.

Overall, consumers agreed with the four objectives. Regarding all the objectives, there is also strong support for specific mention of the needs of people with rare diseases and cancers and the specific challenges they face in access to medicines.

Medical and medicines research and researchers, and research funders must also be included and connected into other aspects of the policy framework. The current NMP is largely silent when it comes to including researchers. We strongly suggest adding a fifth objective relating to a viable medicine research capacity and support for clinical trials. This is echoed in the stakeholder and partnership section of this submission.

Timely access to medicines

The inclusion of timely access to medicines must be considered as a potential stand-alone principle. It should start with a clear definition as to what constitutes timeliness, particularly with life-threatening and often fast-acting illnesses.

Timeliness—and affordability—are missing when it comes to potentially life-saving drugs that are not available in Australia, not available under the PBS, difficult or impossible for some consumers to access due to where they live or are otherwise unavailable. When it comes to access, there must be explicit mention of rural and remote consumers for whom the tyranny of distance remains a fundamental stumbling block in the delivery of equitable healthcare.

Timeliness is an “overarching aspect” of a national medicines policy. Its mention must include detail and more explanation as to where and how it is being addressed. Overall, there are not sufficient parameters in the policy around what is considered timely.

Quality Use of Medicines

The concept of quality use of medicines is central to the NMP and so needs to be included. However, the term, the Quality Use of Medicines, is not well understood by consumers. Questions asked by consumers about QUM included: “Is it about a more appropriate use of medicines? Is it about access to medicines? Is it when some people have to go overseas just to get medicines not available in Australia?”

While there is a national strategy for QUM, and the term is recognised worldwide within the health sector, it means little to the patient or consumer at the grassroots level. As with a lot of the consumer feedback received by CHF, there is a desperate need for clear, plain English messaging for consumers. QUM is also essential to the NMP and needs to be broadened throughout the whole policy.

QUM needs to be clearer about who has responsibilities for quality use of medicine, what those responsibilities are for each group and how they can be measured.

Maintain a viable and responsible medicines industry

The increase in use and dependency on medicines, devices and diagnostics means we need to rethink how we remunerate and incentivise industry to develop new antimicrobials. Providing remuneration and incentives based on medicine sales, as per their unit price multiplied by volume of sales, is no longer a rational approach when medicines need to be used judiciously. It is potentially harming the health and the hip-pocket of consumers.

The other end of this increased use of medicines is the increase in pharmaceutical waste disposal. Environmental protection and the management and disposal of unsafe and unwanted medicines must be further considered, and guidelines developed in any policy update. The National Return and Disposal of Unwanted Medicines (RUM) program has been in place since 1996 but recent research suggests few Australians are aware of it. There remains a trend in Australia toward inappropriate medicine disposal practices and a lack of understanding of the risks of the inappropriate disposal of medicines.⁷

⁷ Bettington, E., Spinks, J., Kelly, F., Gallardo-Godoy, A., Nghiem, S. and Wheeler, A.J., 2018. When is a medicine unwanted, how is it disposed, and how might safe disposal be promoted? Insights from the Australian population. *Australian Health Review*, 42(6), pp.709-717.

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

Question: 2A

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?

The NMP must be clearly delineated so that the definition of medicines be broad enough to encompass health technologies and innovations associated with the delivery of medicines.

If the scope changes too much to include all health technologies, the name of the policy would have to change or include subordinate policies such as a medical device and technology policy, and a broader HTA that frames both policies.

The recommendation is to broaden the definition of medicine to include the means of delivering that medicine. This would in part get over the current disconnect between medicines and the devices sometimes used to deliver those medicines. Broadening the definition in this fashion will not run the risk of losing the consumer benefits on medicines. Broadening the definition could have the benefits of alignment and be a better reflection of the lived reality—those medicines often go alongside medicine delivery devices and other similar technologies.

Question: 2B

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?

The core focus of the NMP, according to consumer feedback, should be about how we access medicines (and associated technologies) rather than what is included in the definition or the title: "Maintaining a level of encompassing language will include other therapies and treatments rather than it being about a medicine or a specific technology."

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

Question: 3A

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

The NMP was developed over 20 years ago and the lack of any review means it has not kept pace with the many and varied changes to the environment in which it is operating

We have seen changes in hospital utilisation with hospital stays have been reduced drastically, so more care is being delivered in people's homes/residential care, more care is self-managed or managed in community health centres. Consumers have shown a growing preference for services to be delivered at home and so we are likely to see this trend continue,

and the pace of change accelerate. Indeed, in the COVID pandemic we have seen more complex cases cared for in hospital in the home programs than previously.

The introduction of the NDIS and the impact on people with chronic illnesses, including the lack of support for medicines management in the NDIS system has an impact on how we ensure the quality use of medicines.

The changes in the burden of disease with the shift to chronic and complex diseases and an increase in polypharmacy again puts pressure on the quality use of medicines by making the task more complex for both consumers, prescribers and dispensers.

The description of Quality use of Medicines and the expectations around programs which seek to ensure it is in place need to better reflect these changes.

Because of this there is more room for there to be gaps in care, which can lead to preventable harm. Consequently, more, and better funding needs to be directed to those health services that provide non-pharmacological therapies and other treatments alongside drug treatment options.

There is a set of National Indicators for the Quality Use of Medicines in Australian Hospitals from 2014, and this includes continuity of care when patients are discharged, but there are currently no indicators specifically for community care. This must be considered when reviewing this policy.

Innovation

Important developments in science and technology are leading to dramatic changes in healthcare and the need for Health Technology Assessments (HTAs). We are seeing new vaccines and medications and emerging novel medical technologies particularly in the areas of biologics, cell and gene (modified) therapies; tumour agnostic (histology and site independent) cancer therapies. Translational research is moving basic science discoveries more quickly and efficiently into practice, as we have seen with COVID-19 vaccines. Big data and precision medicine all have a role to play. Importantly, the NMP must be clear about its relationship with Health Technology Assessments (HTAs) and how the process is covered within the principle of timeliness and equity for consumers.

The revised policy needs to be technologically agnostic with asset of principles and objectives that are flexible enough to encompass as yet unknown technological breakthrough and offer consumers assurance that they will be able to access them.

Clinical trials and medicines access programs

The link between the NMP and clinical trials and medicines access is to clarify and strengthen the relationships between stakeholders and keeping equity for consumers at the centre of this policy. The lack of general consumer knowledge about Australian Clinical Trials is just one example of how and why lifesaving drugs may often not end up being registered in Australia. Public communication about the existence of such trials and other ways to access lifesaving medicines must be strengthened. Public communications around the need for a diversity of consumers must be considered for clinical trials as much as it must be incorporated into all medicines processes.

An important part of research and development for new medicines and medical technologies is clinical research trials. By being involved in clinical trials, Australians (including patient

advocates and clinicians) can have a greater say in their design including who is involved, for how long, and which outcomes are measured. Patient reported experience and outcome measures must be included in design: quality of life is important and often not considered in clinical trials and the HTA process.

Jurisdictional differences are making access to affordable and off-label medicine inequitable. Regional, rural and remote health cannot be left behind when it comes to funding for community-based health and involvement in clinical trials and medicines access programs. This includes access in and to quality aged care. Considering that Australia has the highest poverty rate in the OECD for aged pensioners,⁸ the inequalities around aged care have been a sad and awful highlight of COVID-19.

The NMP could also proactively encourage investigational drugs to contribute our ideals of integrity and value for money to the global community by being involved in co-designing research in multicentre clinical trials.

The uncertainty around funding mechanisms in Australia means there is reluctance with pharmaceutical companies to invest in and conduct clinical trials, particularly for rare diseases. Clinical trials build the expertise and preparedness of our health system in working with, and improving new, innovative technologies.

To ensure HTAs are conducted in the interest of patients there needs to be a clear and meaningful role for patients, carers and patient advocates in clinical assessments and appraisals along the entire HTA pathway, from scoping and prioritisation of HTAs to the development of recommendations and dissemination. Standardising clinical assessments must be included. There are two key areas that enable access to new medicines and medical technologies in Australia: the process for registering a product for marketing in Australia (regulatory) and the process to achieve government reimbursement (through PBAC, MSAC and the Prostheses List Advisory Committee).

Health literacy

We are calling for much greater focus on health literacy for both consumers and within organisations in the NMP.

The term Health literacy may not be common to grass-roots consumers, but it is a commonly used term world-wide at the systems advocacy level. While discussions around health literacy point to a deficit view regarding consumers' lack of understanding, it is the responsibility of industry and government to speak in a language that consumers understand. Focusing on the capacity to improve communications would be a bonus for consumers when it comes to keeping up with a rapidly evolving health world. There is a massive disconnect between consumers and communicators/stakeholders:

“The medicines policy is for us so we should be able to understand it.”

Health clinicians must be accountable and responsible for conveying messages to the consumer in a way that can be understood, and in a place where the message can be received. CHF's Consumer Health Literacy Segmentation Research Project, commissioned by

⁸ Organization for Economic Cooperation and Development, 2019. *Pensions at a glance 2019: How does Australia compare?* <http://www.oecd.org/els/public-pensions/oecd-pensions-at-a-glance-19991363.htm> Accessed 23 March 2021.

NPS MedicineWise, identified from a survey of more than 1,500 respondents, that approximately one in five consumers:

- Rarely or never felt comfortable asking their doctor, pharmacist or nurse when they needed more information
- Rarely or never felt comfortable asking the health professional to explain anything they didn't understand
- Found the information a health professional gave them always or often confusing.

Clinicians provide for a system of care in which consumers must be able to build their health literacy, as partners in the delivery of QUM. The system is accountable to the consumer, not the other way around.

Consumers are calling for much greater collaboration with the TGA for there to be full stakeholder and industry engagement around health literacy. The TGA needs to be able to tell industry what clear communication looks like for different demographics. There is a need for that strength from a government perspective.

Consumers need basic, respectful communications strategies for the whole community, not seven-page Consumer Medicines Information sheets (CMIs) printed in miniscule jargon that consumers are never going to read, need or understand.

Consumers have much greater access to information about medicines and health than ever before.⁹ The internet has become a vital source of information for those who have access to it, with those people more likely to conduct an internet search than to speak to a primary health clinician.¹⁰ People expect a large amount of information to be easily available in a format that they understand and in a place that is easy to find and from a reliable source.

How we increase health literacy and make necessary changes comes back to change management processes including using objective data, the use of technology and good policies around achieving the quality use of medicines. We need to educate and train government, industry, and clinicians in the use of plain English and clear communications, and consumers must be educated about public health.

Responsibility for increasing QUM literacy and health literacy tools must be shared between government organisations and health care professionals, to continue improving health literacy for consumers regarding self-care.

With improved health literacy in mind, there is a lot of misinformation on the Internet and people need to know which apps or which websites to trust. In research currently being undertaken by CHF, findings are showing that any discussion around QUM must start in the consultation between the GP and the consumer. Primary Health Networks (PHNs), consumers and clinicians all agree that having prompts at hand to guide those discussions must be available for consumer and clinicians while the initial conversation is taking place.¹¹

⁹ McLachlan, A. J., & Aslani, P., 2020. National Medicines Policy 2.0: a vision for the future. *Australian prescriber*.

¹⁰ Australian Department of Health, 2021. Consumer Health Literacy Segmentation Research. Consumers Health Forum of Australia.

¹¹ Consumers Health Forum of Australia, 2021. *Supporting Primary Health Networks to build health literacy to improve the quality use of medicines in their communities* (unpublished)

Equity and sustainability

Vulnerable people—the elderly, Indigenous people, refugees, migrants, those with disabilities, and those living with mental illness (for whom poor outcomes have escalated over the past 20 years)¹²—need to be included in the patient-centred focus. The spectrum for health providers is possibly wider than it has ever been.

The role of carers—formal and informal—must be further considered. Older people are often accompanied by family members and carers, who play an important role in their care and advocacy. Many others bring advocates or carers into the health care setting, whether for cultural safety, linguistically, for the neuro-diverse or otherwise; so, health providers are dealing with more than just the patient on a regular basis.¹³ People with multiple chronic conditions also require greater care and are often less able to be proactive and manage their medicines.¹⁴

Limited interpreter services within the health system mean that family members, including children, can often be the primary translators for migrants and refugees.¹⁵

The pandemic has highlighted many cracks in our society, such as the casualization of the workforce, inadequate income support for pensioners of all kinds, and quality and affordable housing which is associated with better health.¹⁶ Current funding mechanisms need to be addressed nationally.

Real-World Evidence

Connected information systems can be very helpful in capturing and analysing real-world data. For that picture to be comprehensive, the data-gathering must be systemic: data collection, collation, storage, and analysis can all be used to inform health policy development to include web-based systems.

The current My Health Record capabilities in Australia have seen legal and ethical issues arise around equal access for people with communication disabilities¹⁷; privacy issues regarding the opt-out model¹⁸ and gaps remain in the quality and usability of information “which may negatively impact the ability for people with low health literacy to access and use MyHR”¹⁹.

¹² McLachlan, A. J., & Aslani, P., 2020. National Medicines Policy 2.0: a vision for the future. *Australian prescriber*.

¹³ Mackie, B.R., Mitchell, M. and Marshall, A.P., 2019. Patient and family members' perceptions of family participation in care on acute care wards. *Scandinavian journal of caring sciences*, 33(2), pp.359-370.

¹⁴ Stewart, D., Mair, A., Wilson, M., Kardas, P., Lewek, P., Alonso, A., McIntosh, J., MacLure, K. and SIMPATHY consortium, 2017. Guidance to manage inappropriate polypharmacy in older people: systematic review and future developments. *Expert opinion on drug safety*, 16(2), pp.203-213.

¹⁵ Pines, R.L., Jones, L. and Sheeran, N., 2020. Using family members as medical interpreters: An explanation of healthcare practitioners' normative practices in pediatric and neonatal departments in Australia. *Health communication*, 35(7), pp.902-909.

¹⁶ Janet Ige, Paul Pilkington, Judy Orme, Ben Williams, Emily Prestwood, D Black, Laurence Carmichael, Gabriel Scally, 2019. The relationship between buildings and health: a systematic review, *Journal of Public Health*, Volume 41, Issue 2, June 2019, Pages e121–e132, <https://doi.org/10.1093/pubmed/fdy138>

¹⁷ Hemsley, B., McCarthy, S., Adams, N., Georgiou, A., Hill, S. and Balandin, S., 2018. Legal, ethical, and rights issues in the adoption and use of the “My Health Record” by people with communication disability in Australia. *Journal of Intellectual & Developmental Disability*, 43(4), pp.506-514.

¹⁸ Pang, P.C.I., McKay, D., Chang, S., Chen, Q., Zhang, X. and Cui, L., 2020. Privacy concerns of the Australian My Health Record: Implications for other large-scale opt-out personal health records. *Information Processing & Management*, 57(6), p.102364.

¹⁹ Walsh, L., Hemsley, B., Allan, M., Dahm, M.R., Balandin, S., Georgiou, A., Higgins, I., McCarthy, S. and Hill, S., 2021. Assessing the information quality and usability of My Health Record within a health literacy framework: What's changed since 2016? *Health Information Management Journal*, 50(1-2), pp.13-25.

It needs to be clear how the NMP remains relevant in relation to the development of digital infrastructure to capture data on health outcomes in the short and longer term so that we can collect, use, and learn from real world data and evidence. HTAs can play a key role in providing equitable and sustainable universal healthcare.

Drug Repurposing

The NMP must be inclusive of new uses and novel uses for existing medicines and other associated technologies, particularly where there is an unmet need, in particular orphan, personalised and off-patent drugs that could be repurposed and used to treat new conditions and/or used in precision medicine. Repurposing is a disjointed process that is often not funded for rare indications. There is little to no data collection and no rigour. Consumer feedback indicates a strong desire to include drugs that might otherwise not fall within the policy.

Development of vaccines and treatments for COVID-19 and 'Long COVID', for example, have been based on novel uses for existing medicines and other technologies. Repurposing existing therapies may allow patients faster access to medicines. Elevate the inclusion of repurposing existing medicines into novel treatment research funding options. The current preconception that profit is necessary to make research into repurposing medicines fruitful is restricting what makes it into the drug development pipeline. Increase funding for research into novel treatment options particularly for rare diseases, which are often not suited to standard double-blind placebo-controlled research. If HTAs are part of the framework, there needs to be a reduction in the reliance on sponsor led HTAs to open the path for other, non-commercially viable medicines to be included.

Digital health

The first thing that must be remembered when discussing digital health is that 10 to 20 percent of Australians do not have access to the internet.²⁰ This lack of access is a key driver of inequity in Australia. For digital health to be equitable, the fundamental lack of internet for so many Australians must be recognised and addressed.

For those who do have access to the internet, digital health initiatives could have a major impact on the quality use of medicines and implementation of the NMP. Strategies like the national digital health record system, electronic medication management and real-time prescription monitoring can help reduce preventable harm and improve the quality use of medicines for consumers. But they must be fully implemented across the health sector. Developing a systemic role for digital and virtual health care is vital. Using a range of digital tools, personalising health and wellness programs and linking with specialist call centres are all necessary and achievable—if the diverse needs of all Australians are considered and included. This includes those who would also rather have face-to-face appointments with health clinicians than use telehealth.

Consumers would like to see a much greater focus on patient wishes and respect for patient privacy in the increasing digital world. There are still great concerns about patient data and how it is conveyed. One suggestion is that medical software include options for preferred communications methods for patients.

Something that COVID-19 has taught us, is that the health of the community is inextricable from the economy. With massive unemployment, increase in telehealth has made access to

²⁰ Australian Bureau of Statistics, 2018. *Household use of information technology*, <https://bit.ly/3ojlVUt>

health care that little bit easier for most consumers. And that needs to continue. But more needs to be invested, particularly for vulnerable community members who might find technology difficult for all sorts of reasons (such as language difficulties, hearing difficulties, neuro-diverse patients, or technology-related issues).

Question: 3B

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?

Consumers agreed that the NMP has not kept up with changes in the health system and the policy environment. Keeping the policy refreshed and up to date requires annual reviews. This is common in medicines policies in other countries. To address future changes and to future-proof the NMP it must:

- Be technologically agnostic—so do not link policy to existing technologies but rather focus on what outcome that part of the policy is trying to achieve
- Have regular scheduled reviews of the NMP and a mechanism for collecting feedback to inform those reviews including where new technologies do not seem to fit
- Make it a more dynamic living document not set in stone and so not viewed as sacrosanct
- Ensure other policy developments such as 10-year primary health reform take account of national medicines policy and are informed by it and in return inform any reviews.

As a high-level policy, the NMP needs to clearly lay out a map that show how the NMP links directly to the ground-level experience of consumers and primary health clinicians. The map must show how other documents and/or policies are fed by the NMP; how they are carried out who is responsible for what. For example, a link between the NMP and the consumer regarding QUM could be the availability of patient prompts such as a take-home or online information along the lines of the *Choosing Wisely 5 Questions to ask your doctor*, namely *5 Questions to ask about your medication*. The map would link the patient to the online resources and link the patient to primary care clinicians who would also be responsible for ensuring the patient has access to such prompts.

Consumer-level documents or prompts such as these do not need to be part of the NMP, but they are informed by it, fed by it and are part of the government's QUM strategy. The average consumer needs to see how the NMP is working for them, for example, through the Pharmaceutical Benefits Advisory Committee (PBAC), the Pharmaceutical Benefits Scheme (PBS) and through QUM.

To be a dynamic system, initiatives might stem from policy teamwork such as literacy programs/advocacy, translation, or multimedia resources.

4. Consider the centrality of the consumer within the NMP and whether it captures the diversity of consumers, and their needs and expectations.

Question: 4A

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

This should have been the first question asked by the NMP review committee.

There has been a shift over the past 22 years in the behaviour of consumers. Change theory and community development principles recognise that we need to identify the conditions and contexts that have led to change to determine what conditions and outcomes need to be achieved for new goals to occur.²¹

If this policy is for the benefit of consumers, then a focus on consumer-centric interaction must go right back to the grassroots of respectful language and be relevant and meaningful to the consumer. 'Consider the centricity of the consumer' is not plain English. Appropriate engagement and specificity around language and reaching the diversity of consumers must be a factor in communications around the consumer focus. The consumer feedback is clear: Messages are not being received in the way consumers need to receive them. Consumers need to be asked what their needs and expectations are and then those needs must be addressed.

The centricity of the consumer is not a tick-box compliance measure. Consumer centricity must underscore every level of this policy to the point that the need for looking at the diversity of consumers should be an explicit statement in the policy. It is vital that this policy ensures that a diversity of consumer input is included at all levels of policy development and in monitoring further reviews of the NMP.

The policy should also consider the growth in health consumers (associated with patient organisations) and the desire for consumers to be more involved in their own medicines.

Consumers want more information and want shared decision-making in all aspects of their medical care including the use of medicines, but consumers need the tools and information to be able to participate. This should also be reflected in all other aspects of this policy.

As a central principle of the NMP is about keeping the consumer at the centre of a co-created experience, there is a growing expectation that consumers be informed and active in managing their own health and health care.²² For consumers to cope in this new environment, they need greater competencies, including health literacy, numeracy, and greater patient activation.²³

Consumers want to be involved in decision-making regarding the availability of medicines such as has been seen with push to have more consumer impact into PBAC and the establishment of the Health Technology Assessment Consumer Consultative Committee. The multiplicity of roles of consumers is set out in CHF's *Shifting Gears* white paper.²⁴ The paper

²¹ Connell, J.P. and Kubisch, A.C., 1998. Applying a theory of change approach to the evaluation of comprehensive community initiatives: progress, prospects, and problems. *New approaches to evaluating community initiatives*, 2(15-44), pp.1-16.

²² Hibbard, J.H., Peters, E., Dixon, A. and Tusler, M., 2007. Consumer competencies and the use of comparative quality information: it isn't just about literacy. *Medical Care Research and Review*, 64(4), pp.379-394.

²³ Consumers Health Forum of Australia, October 2019. Patient Activation in Australians with Chronic Illness – Survey Results. 20191030_rpt_patient_activation_survey_report_final.pdf (chf.org.au). Accessed 17 March 2021.

²⁴ Consumers Health Forum of Australia, 2018. *Shifting Gears: Consumers transforming health* <https://bit.ly/3uq7znl>

describes the major shifts that need to occur in health policy if our system is to be people-centred and sustainable. It highlights that the consumer role in health is not one-dimensional but has many roles and functions. The roles and responsibilities, skills, and knowledge that consumers can contribute to the health system is an emerging one.

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

Consumers need clear information, including information about their responsibilities as co-creators of their own health care. Health providers also need to be better equipped to deal with people who are aware of the broader spectrum of treatments that are now available. Health providers need sufficient knowledge of proven therapies and their effective integration into the health care delivery system.²⁵ Medication safety and efficacy therefore needs much greater surveillance. Training and credentials in the quality use of medicines—particularly in combination with other treatments—is more important than ever for primary health carers.

Question: 5A

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

The NMP must have an overarching committee to oversee the policy's implementation and reviews, and to provide advice where required. The committee must be consumer-centric in having equal numbers of consumers to clinicians, researchers, administrators, and other stakeholders, and include a diverse mix among all committee members. Diversity must be fundamental in both the compiling of this policy and in its governance. It is not enough to consult with consumers after the fact or in a separate advisory body. They must be included and fundamental to the policy's management. Having diverse representatives on the committee will build sustainability and agility into policy.

The consumers on the committee need to be selected from among those with good consumer connections, who are actively involved in or with consumer organisations, community organisations or other active consumer-based involvement.

There also must be underpinning mechanisms to support consumers in their role on the committee, particularly in facilitating them in consulting with a broader range of consumers.

Clear terms of reference and transparent processes are also vital.

The Australian consumer is the beneficiary of this policy. This is who the policy and the committee that oversees it are accountable to. This should be made explicit.

There should be an annual National Medicines Policy Forum, led by the committee. Both the committee and the forum should be set out in the Policy. There are many possible formats for such a Forum, but it should be co- designed with consumer organisations to ensure it meets consumer needs for accountability and transparency. Consumer organisations and

²⁵ Wagner, C., 2020. *Complementary and alternative medicine*. The United States Healthcare System: Overview, Driving Forces, and Outlook for the Future. Chicago, IL: Health Administration Press.

some individual consumers should be supported to participate in the forum to ensure their involvement is more than just tokenism.

Question: 5B

How can communication about the NMP be enhanced or improved?

There must be an initial consumer awareness campaign for the new NMP and what it means for consumers. This is where consumer-centric terminology, and the integral inclusion of the consumer in the NMP will be so important. Reinforcing inclusion and diversity in the terminology will reinforce the consumer's position as the end-user of this critical policy. It is key that the methodology behind the policy be explained.

Question: 5C

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

If the policy is to be meaningful and continue to be impactful and relevant for the end user, it must be accompanied by a plain language consumer guide that explains the relevance of the NMP, patient rights and responsibilities, shared decision-making and the role of diversity and inclusivity as a basis of the policy.

Conduct regular communications through media for the general public; community announcements on any and all consumer-related supports such as reliable websites, reliable medicines telephone supports, fact sheets or prompts such as *5 Questions to ask about your medication*, similar health literacy-related supports or other QUM and medicine-related support in primary health care; provide plain language documents consumers can refer to; consider messaging and communications that are appropriate and relevant to diverse consumer needs at any given time.

The policy principles of accountability and transparency must be highlighted. Consumers need to know how the NMP's principles are being enacted.

Evaluation

Embedding evaluation, KPIs and measuring within the policy is vital. To this end, the NMP must be evaluated and measured regularly. The policy should set out the core ways impact will be measured, for example: medicine safety; fewer adverse effects; improvements in the quality use of medicines in primary health care; the development and use of tools to build health literacy and quality use of medicines; the development and outcomes of partnerships in developing consumer involvement. It is vital that the actions, outcomes and impacts that result from this policy are measured.

It is vital that an updated NMP measures health outcome so that the focus is on what is valued and what is relevant to patients. This is also important in terms of where to direct funding. The basic principles underlying all policy must be based on clear and up-to-date data.

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

Question: 6A

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

A list of stakeholders and the stakeholder map, including affiliations, shareholdings and other potential COIs must be developed so that:

- a) The partnership approach can be defined
- b) It will be clear what and who is missing from the list of partners
- c) There is greater accountability among partners
- d) Conflict and conflict of interests can be managed.

Question: 6B

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?

Researchers and research funders are missing from the partners list.

There needs to be a concerted change in building genuine collaborations between health providers of all kinds, aimed at customised patient-driven care. There needs to be an awareness campaign for policy makers, politicians, the private sector, other stakeholders, and the community on what the National Medicines Policy is and how it plays out in the lives of consumers.

Question: 6C

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

The NMP must be reviewed annually to identify gaps that can then be addressed.

Annual public hearings of the committee will allow consumers and other stakeholders to raise issues especially where they see the NMP principles not being adhered to in other policies or initiatives. Those responsible for the enactment of the policy are also responsible to the end user: the consumer. By conducting annual committee reviews, it means it is not just the loudest voices that get the focus.

Clearly articulated links between the NMP and other policies, programs and initiatives and clearly identified KPIs must be reported on annually.

Having KPIs and conducting annual reviews by a diverse NMP committee will build regular, longitudinal measurement into the policy. It will encourage regular communication and engagement with stakeholders and consumers.

Question: 6D

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

There must be a published, public register of stakeholder organisations, their roles and membership, and their avenue of funding to declare Conflicts of interest (COIs). This includes any consultancy work they may do. Shareholdings must also be declared, as well as any link to any roles on behalf of pharmaceutical companies. COIs are necessary to ensuring critical motivations.

Closer partnerships and genuine collaborations between stakeholders, such as the ongoing relationships between the Consumers Health Forum and organisations like NPS MedicineWise and Medicines Australia, must continue to be fostered. More funding, then, needs to be directed to those bodies that monitor, support and advocate for improvements in policy.

Conclusion

CHF's goal is to shape better health care by ensuring that the primacy of the consumer remains front and centre of policy development. This development must include a clear plan and commitment to fully implement new guidelines and systems for there to be any real change and improvement to health care in Australia.

Data measuring and evaluation must be prioritised for real world impact to continue and so that regular and appropriate adaptations can take place. This will also continue to strengthen and focus funding decisions in the dynamic and ever-changing world of health care. The ultimate results will be better data, better health outcomes, better partnerships, and a better future for all.

The national medicines policy must be updated so that it can be adaptive to the many new medicines, therapies, challenges, and opportunities that present themselves every day in the health sector.

The committee must seek out diverse consumer feedback and provide time for consumers to have further input into the draft of the new NMP before it is finalised.

With changes in policy, we are going to need a clear plan of action and strategies to realise those changes; regular reviews of the policy and the strategies so that consumers are not waiting another 22 years during which time we could be missing opportunities, or harm could be caused, because we weren't keeping up. Having a National Medicines Policy that includes room for adaptation and progress for consumers is vital in delivering optimal health outcomes.