NACCHO
National Aboriginal Community Controlled Health Organisation
Aboriginal health in Aboriginal hands
www.naccho.org.au

National Medicines Policy Review

NACCHO Submission

October 2021

About NACCHO

NACCHO is the national peak body representing 143 Aboriginal Community Controlled Health Organisations (ACCHOs) Australia wide on Aboriginal and Torres Strait Islander health and wellbeing issues. NACCHO's work is focused on liaising with governments, its membership, and other organisations on health and wellbeing policy and planning issues and advocacy relating to health service delivery, health information, research, public health, health financing and health programs. Our members provide about three million episodes of care per year for about 350,000 people across Australia, including about one million episodes of care in very remote regions.

Sector Support Organisations, also known as affiliates, are State based and represent ACCHOs offering a wide range of support services and Aboriginal and Torres Strait Islander health programs to their members including advocacy, governance and the delivery of state, territory and national primary health care policies.

ACCHOs range from large multi-functional services employing several medical practitioners and providing a wide range of services, to small services which rely on Aboriginal Health Workers/Practitioners and/or nurses to provide the bulk of primary health care services, often with a preventive, health education focus. Our 143 ACCHOs operate approximately 700 facilities, including about 450 clinics. ACCHOs and their facilities and clinics contribute to improving Aboriginal and Torres Strait Islander health and wellbeing through the provision of comprehensive holistic primary health care, and by integrating and coordinating care and services. Many provide home and site visits; medical, public health and health promotion services; allied health; nursing services; assistance with making appointments and transport; help accessing childcare or dealing with the justice system; drug and alcohol services; and help with income support. Collectively, we employ about 6,000 staff, 56 per cent of whom are Indigenous, making us the second largest employer of Aboriginal and Torres Strait Islander people in the country.

NACCHO has played a leading role in establishing the Coalition of Peaks; a group of over 50 Aboriginal organisations uniting to negotiate the new National Agreement on Closing the Gap with Australian governments. NACCHO is committed to the objectives underpinning this seminal agreement – much of which can be related to medicines policy reform – and fully support the four-priority reform areas:

1. ***Shared decision-making**: Aboriginal and Torres Strait Islander people are empowered to share decision-making authority with governments to accelerate policy and place-based progress on Closing the Gap through formal partnership arrangements.*
2. ***Building the community-controlled sector:** There is a strong and sustainable Aboriginal and Torres Strait Islander community-controlled sector delivering high quality services to meet the needs of Aboriginal and Torres Strait Islander people across the country.*
3. ***Improving mainstream institutions:** Governments, their organisations and their institutions are accountable for Closing the Gap and are culturally safe and responsive to the needs of Aboriginal and Torres Strait Islander people, including through the services they fund.*
4. ***Aboriginal and Torres Strait Islander-led data:** Aboriginal and Torres Strait Islander people have access to, and the capability to use, locally-relevant data and information to set and monitor the implementation of efforts to close the gap, their priorities and drive their own development.*

About this submission

This submission has been informed by extensive sector, stakeholder, NACCHO staff and subject matter expert consultation, as well as from previous NACCHO medicines research and policy. Consultation has involved circulation to all NACCHO affiliates, including CEOs and Public Health Medical Officers; Aboriginal and Torres Strait Islander clinical representatives, including members of the ACCHO Pharmacist Leadership Group; several medical and pharmacy peak bodies; many key medicines sector NGOs, patient groups and companies; and in consideration of direct commentary provided by NMP Review Committee members and Department of Health and relevant agency representatives (e.g. PBAC). This may be read in conjunction with NACCHO's submission to the House of Representatives *Inquiry into approval processes for new drugs and novel medical technologies in Australia – linked here*.

Executive Summary

Aboriginal and Torres Strait Islander people have led holistic and comprehensive primary healthcare in Australia for over 50 years and Aboriginal and Torres Strait Islander community-controlled organisations' models of care continue to be delivered in a way that is relevant and responsive to their respective communities' needs. However, despite the strengths within Aboriginal and Torres Strait Islander approaches to well-being, systemic bias and racism continues in Australia's health environment, and health inequity compared to other Australians persists. Since the publication of the National Medicines Policy (NMP) in 2000, there have been several programs and measures that aim to improve how medicines are accessed and used by Aboriginal and Torres Strait Islander people. Outcomes for these programs have not been adequately measured and monitoring and evaluation of medicines activities for Aboriginal and Torres Strait Islander is poorly resourced and coordinated. While it appears that these programs and measures have had some impact, recent Australian Government data demonstrate continued grossly inequitable medicines access and expenditure for Aboriginal and Torres Strait Islander people. Ultimately, Australia's NMP has been unable to consistently guide the development of medicine policy in an equitable way that would significantly impact the medicines use and health of Aboriginal and Torres Strait Islander people. This has been compounded by an overall lack of transparency and accountability related to the policy. In consideration of the current situation, it is timely that a refreshed national policy approach to medicines is being taken through this review.

The "collaborative partnerships" referenced in current NMP largely do not currently function effectively and many medicines agencies' responsiveness to Aboriginal and Torres Strait Islander peoples' needs is inadequate. There is a need for structural reform for the entire medicines sector in the way that it serves Aboriginal and Torres Strait Islander peoples' medicines needs. Such reform must be reflected more clearly in the new NMP and is congruent with overarching Aboriginal and Torres Strait Islander policy, including the Australian governments' commitment to the objectives underpinning the new National Agreement on Closing the Gap, and the priority reforms areas within this policy.

Despite the need for structural change to Aboriginal and Torres Strait Islander peoples' needs, a refreshed NMP may largely retain its essential themes. It should remain concise and clear and continue to reflect inclusivity and a shared vision.

"The purpose of the NMP is not to be a large collection of guidelines or processes but a set of principles which underpin and are core to policy development, the strategizing of policy, implementation and evaluation."

Lloyd Sansom, Jan 2020

We have identified several specific areas within the NMP where amendment or enhancement would have a manifest impact on Aboriginal and Torres Strait Islander health outcomes. The policy itself must be accompanied by clear and sustained governance, implementation, monitoring and evaluation processes, which focus on health outcomes. Under such features, the current disparity between Aboriginal and Torres Strait Islander people and other Australians necessitates a distinct national Aboriginal and Torres Strait Islander medicines advisory group or body, that may provide strategic advice and governance at the level required to achieve true reform – this body may be referenced directly in the NMP. Such a body may advise on medicines and health research, health technology assessment, governance, healthcare service provision and therapeutic regulation for Aboriginal and Torres Strait Islander people.

We note the documented inequity Aboriginal and Torres Strait Islander people face compared to other Australians related to Quality Use of Medicines (QUM), and the lack of QUM outcomes measurement data currently available. Therefore, the discussion in the NMP related to access to medicines and QUM services should be enhanced with greater consideration of specific known challenges that exist for Aboriginal and Torres Strait Islander people, including cultural safety, health literacy, geographical access disparities, shortage and supply challenges and more.

Medicines alone won't solve health disparities – related services, policies and the system generally must be considered within the NMP. To ensure that the policy has maximum impact, the NMP should be broadly consistent with other key national health policy and implementation plans, such as primary care strategies, health care professional education, hospital policies, Aboriginal and Torres Strait Islander health policies and models of care, health workforce policy, and more. A greater consideration of a more comprehensive health systems approach is required within the NMP, especially in relation to the multiple dimensions of medicines adherence. Similarly, the broad concepts within the Quadruple Aim of healthcare should be considered – enhancing the patient experience, improving public health, reducing costs, and improving the work life of health care providers – to ensure the needs of all stakeholders in the medicines sector are met. Further to this, the document may acknowledge the broader health, social and economic impacts of medicines, for example societal benefits derived through opioid replacement treatment.

The policy must truly capture the consistent reference to equity provided through NMP workshops and the Review Committee so far. Currently, the word equity is applied too generally in the Terms of Reference and NMP itself, which diminishes the impact and importance of this concept. Therefore, the reference to equity must be significantly expanded, applied throughout the policy and based in practical and explicit issues to ensure accountability of all parties. The NMP should also draw from contemporary international medicines policy, such as World Health Organisation (WHO) medicines policy and other countries' Health Technology Assessment policies.

The NMP must make clearer reference to medicines access, safety and pharmacovigilance, including the specific challenges facing Aboriginal and Torres Strait Islander people in these areas.

Finally, in such policy reform, this refreshed NMP may define a new level of quality in medicines policy to be lauded as a world-leading approach. With such vision and the appropriate governance, this policy stands to be truly successful in improving outcomes for all Australians for years to come.

List of recommendations (condensed)

A. NACCHO Overarching Recommendations

Partnerships and collaboration with Aboriginal and Torres Strait Islander people

Recommendation 1:
The NMP should provide commentary and conceptual alignment with governments' overarching commitments to Aboriginal and Torres Strait Islander health reform, and with acknowledgement of broader Aboriginal and Torres Strait Islander policies and principles.

Recommendation 2:
The NMP should include reference to a principal Aboriginal and Torres Strait Islander medicines advisory body. This body could be undertaken in partnership between NACCHO and Commonwealth.

Recommendation 3:
The NMP should support Aboriginal and Torres Strait Islander participation in leadership and oversight in all national medicines committees, organisations and agencies.

Recommendation 4:[a]
Aboriginal and Torres Strait Islander representatives must participate substantively in NMP Review virtual group discussions. This may include one or more sessions specifically involving Aboriginal and Torres Strait Islander people only.

Governance, accountability, monitoring and evaluation

Recommendation 5:
A comprehensive and sustained NMP implementation, communication, monitoring and evaluation strategy/s is required for the life of the policy. All monitoring and evaluation activities must apply an equity lens to ensure Aboriginal and Torres Strait Islander people are benefiting equitably from the policy.

Quality use of medicines

Recommendation 6:
The NMP should take a more health systems approach and make more specific reference to the multiple and validated dimensions of adherence available in the global health literature.

Recommendation 7:
The NMP should make more specific reference to both pharmacist services and to QUM for Aboriginal and Torres Strait Islander people.

Equity

Recommendation 8:
The focus on equity and consideration of systematic bias should be enhanced in the NMP.

Recommendation 9:
In enhancing the focus on equity, the NMP must define the elements of equity much more explicitly and in a way that reflects the practical equity challenges in Australia, including specific reference to inequity issues relevant to Aboriginal and Torres Strait Islander people.

[a] This recommendation is for the NMP Review Committee specifically

Recommendation 10:
Under a 'Challenges' section of the NMP, the inclusion of strategies to mitigate inequity in medicines access, including HTA, should be highlighted.

Recommendation 11:
The specific inclusion of a reference to the importance of cultural safety should be included in the NMP Access objective.

Medicines access, supply and shortages issues

Recommendation 12:
The NMP must be more specific and emphatic in relation to addressing medicines supply and shortage issues.

Medicines safety

Recommendation 13:
The NMP must make clearer reference to pharmacovigilance and medicines safety specifically for Aboriginal and Torres Strait Islander people.

B. NMP Discussion Paper Recommendations

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

Recommendation 14:
The term consumer must be expanded and discussed to allow for a more holistic and culturally appropriate definition to be captured.

Recommendation 15:
Comprehensive state and territory engagement is required throughout the NMP consultation – including with those who work directly with Aboriginal and Torres Strait Islander clients – to ensure that accountability and governance strategies in the NMP have consensus from all jurisdictions.

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

Recommendation 16:
Nationally recognised QUM indicators and QUM monitoring and evaluation should be referenced more clearly in the NMP, with specific or adapted QUM indicators developed by and for Aboriginal and Torres Islander people. Indicators should be incorporated into overall NMP governance processes.

Recommendation 17:
Cultural Intellectual Property (IP) of traditional Aboriginal and Torres Strait Islander medicines should be referenced in the relevant section of the NMP.

Recommendation 18:
Clarify the definition of "industry", which may include expanding from a traditional definition, to ensure that medicines consumers' and health practitioners' commercial needs are met.

Recommendation 19:
The NMP should make reference to all actors included under the term industry being held to account under a national framework akin to the Medicines Australia Code of Conduct.

Question: *Should the current NMP definition of medicines be expanded to include medical devices and vaccines? Why or why not?*

Recommendation 20:
We support the inclusion of vaccines.

Recommendation 21:
While we support the consideration of some relevant medical devices, the unintended consequences of inclusion should be thoroughly considered.

Recommendation 22:
Medicines definition should specifically include traditional Aboriginal and Torres Strait Islander medicines.

Question: *Does the policy's current title, the "National Medicines Policy", reflect the breadth of health technology developments within the policy's scope?*

Recommendation 23:
The title can remain unchanged and definition and associated health activities be discussed clearly and early in the document.

Question: *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?*

Recommendation 24:
The NMP should state that Aboriginal and Torres Strait Islander leadership and translation is required in the development and implementation of policy related to new and evolving treatment options

Recommendation 25:
The NMP should acknowledge the value of understanding and improving health literacy, and may reference strategies that support equity and community-control for Aboriginal and Torres Strait Islander people

Question: *How can communication about the NMP be enhanced or improved?*

Recommendation 26:
Implementation of the refreshed NMP should include a suite of translated materials, which may include plain language summaries and specific reference to what consumers and communities can expect the NMP to deliver, and what to do if they are concerned that this is not happening.

Recommendation 27:
The NMP must reflect that all health care providers should be better educated about the factors that influence medication adherence, including skills-based training on how to address barriers to adherence. Consistent with Recommendation 5, this should be accompanied by health care system performance KPIs, which may include quality assurance activities.

Recommendation 28:
Measurement and evaluation of communication should be incorporated into indicators and governance.

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

Recommendation 29:
Aboriginal and Torres Strait Islander peak bodies and the relevant Aboriginal and Torres Strait Islander advisory group/s should be involved in communication strategies.

Recommendation 30:
The NMP may reference the need for associated guidelines and policies to link to the NMP (e.g. 7CPA)

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

Recommendation 31:
The NMP may more specifically define partners and sub-groups of partners, such as 'effector arms' of the NMP, which may include TGA, NPS, PBAC etc. This may allow more clearly defined roles and expectations.

Recommendation 32:
Literature-based measures of partnerships should be incorporated into monitoring of the NMP.

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

Recommendation 33:
The NMP indicators should have explicit metrics associated with accountability and partnership, based on appropriate Australian and international literature.

Section A:

NACCHO general response to the Review of the National Medicines Policy

Introduction

NACCHO welcomes the opportunity to provide input into the National Medicines Policy Review. While we accept that many of the ideas in the policy are still very valid today, we acknowledge the need for updating the policy and the relevance and importance of the several themes identified from the initial National Medicines Policy Review Workshop held in Canberra on 30 January 2020. From NACCHO's perspective the themes from this workshop of a) medicines access, b) health literacy and c) governance and accountability should attract particular consideration.

We also acknowledge the merit in the review aim to identify any gaps in the NMP objectives, partnership approach and accountabilities. While the review Terms of Reference and NMP Discussion Paper only contain modest refence to Aboriginal and Torres Strait Islander people, there are some broader themes that are relevant to NACCHO priorities and concerns. This includes consideration of the NMP's utility to Aboriginal and Torres Strait Islander people in the context of evolving treatment options and population changes; how the NMP captures the diversity of consumers and communities, and their needs and expectations; and the options to improve the NMP governance, communications, implementation (including enablers) and evaluation.

However, despite the perceived value of the Terms of Reference and NMP Committee's Discussion Paper, we are concerned about the overall lack of consideration of Aboriginal and Torres Strait Islander peoples' voices. We have therefore drawn from existing medicines priorities, challenges and models identified by NACCHO and in the literature to provide advice and recommendations to decision-makers that are relevant to Aboriginal and Torres Strait Islander people. These recommendations are made in addition to the subsequent response to the Review of the National Medicines Policy Discussion Paper, Terms of Reference (ToR) and accompanying questions – in Section B of this Submission.

Aboriginal and Torres Strait Islander people and medicines

Aboriginal and Torres Strait Islander people have led holistic and comprehensive primary healthcare in Australia for some decades.[1,2] Aboriginal and Torres Strait Islander community-controlled organisations' models of care are responsive to their respective communities' needs, [3] and continue to provide dynamic and responsive services and population-level health solutions in particularly complex and challenging environments. [4,5] However, systemic bias and racism continues in the Australian health environment,[6,7] and health inequity compared to other Australians persists.[8,9] This bias pervades health research, technology assessment, governance, care service provision and therapeutic regulation. Since the publication of the NMP in 2000, there have been several programs and measures to improve how medicines are accessed and used by Aboriginal and Torres Strait Islander people. While these measures have had some impact, recent Australian Government data demonstrate continued grossly inequitable medicines access and expenditure for Aboriginal and Torres Strait Islander people. In 2020, AIHW reported that the total expenditure on pharmaceuticals in Australia for Aboriginal and Torres Strait Islander people was an average of $537 per person, compared to $891 per person for other Australians.[10] Furthermore, while analysis of global data by

the Commonwealth Fund ranked the Australian health system as a whole 2nd in the world, Australia ranked below average in relation to equity and its ability to service subpopulations with lower means and higher health needs.[11]

There is a need for structural reform for the medicines sector and a refreshed approach to medicines access and use for Aboriginal and Torres Strait Islander people. Further consideration should be given to how the policy reflects principles within the Uluru Statement of the Heart. A refreshed NMP may acknowledge the following points:

- Aboriginal and Torres Strait Islander peoples' of Australia are the traditional custodians of our country
- Aboriginal and Torres Strait Islander people as the first people to use medicine in this country
- The impact that Australian governments' policies have had on the health and well-being of Aboriginal and Torres Strait Islander people
- That partners must all commit to truly enshrining respect for Aboriginal and Torres Strait Islander peoples and cultures within the NMP and its related policies

Reform must be reflected more clearly in the new NMP and is entirely consistent with the Australian governments' commitment to the objectives underpinning the new National Agreement on Closing the Gap, perhaps specifically including the priority reforms of:

1. Shared decision-making;
2. Building the Community-Controlled sector;
3. Improving mainstream institutions; and
4. Aboriginal and Torres Strait Islander-led data.

We propose that in this commitment from governments, only through structural reforms that involve shared decision-making, improved Aboriginal and Torres Strait Islander participation and appropriate evaluation and research related to Aboriginal and Torres Strait Islander peoples' access to medicines, may the current Australian governments truly support equitable access and use of medicines for Aboriginal and Torres Strait Islander people.

Partnerships and collaboration with Aboriginal and Torres Strait Islander people

The NMP references partnership and parties working together throughout the document, including all Australian governments. We have observed a pattern of exclusion of Aboriginal and/or Torres Strait Islander representatives from national medicines committees and bodies. The need for structural reform and refocus on collaboration is most ironically highlighted in the omission of any Aboriginal and/or Torres Strait Islander representative on the very committee reviewing the NMP and the NMP ToR Working Group. We are also disappointed that the NMP committee's Terms of Reference do not include any reference to Aboriginal and Torres Strait Islander people, nor many of the priority medicines themes that NACCHO has identified in previous work with government. Further, the Australian Government appears to have omitted any Aboriginal and/or Torres Strait Islander representatives from the Medicines Strategic Agreement 2022-2027 HTA Review Committee. Exclusion of Aboriginal and Torres Strait Islander people from these processes and committees compounds inequity, as representatives who do not participate do not gain the skills, networks and knowledge to reengage in further iterations of the respective policy development and decision-making.

The current NMP references Aboriginal and Torres Strait Islander people in several places. The NMP states that "partnership commitments" and collaborative framework agreements are required to

address underuse of medicines and access barriers that Aboriginal and Torres Strait Islander people face.

> *"companies may not submit a product for evaluation if the likely market for the medicine in Australia is not large or profitable enough to recoup costs, which can present a barrier to access to medicines needed for unusual conditions, including conditions generally found only in particular sections of the population (eg Aboriginal and Torres Strait Islander communities)."*
>
> *"Potential [medicines] underuse also needs to be addressed, despite Government concerns about the costs involved in the use of more expensive, newer medicines. In particular, there are substantial access barriers and evidence of underuse of medicines by Aboriginal and Torres Strait Islander peoples. Partnership commitments to address the issues (eg Framework Agreements on Aboriginal and Torres Strait Islander health) are required."*

While several programs and measures have been undertaken by governments since the development of the first NMP, currently no sustained formal framework, committee or agency exists to specifically address the underuse of medicines for Aboriginal and Torres Strait Islander people through the PBS. We could not identify any member of Australia's HTA committees or boards of national bodies (such as NPS or ACSQHC) who is Aboriginal and Torres Strait Islander or with a primary expertise in Aboriginal and Torres Strait Islander health. Therefore, the NMP needs to significantly strengthen the wording and specificity of its commitment to collaboration and partnerships with Aboriginal and Torres Strait Islander people.

Recommendation 1:
The NMP should provide commentary and conceptual alignment with governments' overarching commitments to Aboriginal and Torres Strait Islander health reform, and with acknowledgement of broader Aboriginal and Torres Strait Islander policies and principles.

Recommendation 2:
The NMP should include reference to a principal Aboriginal and Torres Strait Islander medicines advisory body or group. This advisory group could be undertaken in partnership between NACCHO and Commonwealth.

Recommendation 3:
The NMP should support Aboriginal and Torres Strait Islander participation in leadership and oversight in all national medicines committees, organisations and agencies. In doing so, the NMP may reference the distinct priorities, paradigms and challenges for Aboriginal and Torres Strait Islander people in relation to medicines and health.

Recommendation 4:[b]
Aboriginal and Torres Strait Islander representatives must participate substantively in NMP Review virtual group discussions. This may include one or more sessions specifically involving Aboriginal and Torres Strait Islander people only.

[b] Recommendation for the NMP Review Committee

Governance, accountability, monitoring and evaluation

While the general inclusive wording within such a short policy document has brought stakeholders and decision-makers together in consensus, statements that are too ambiguous or generic also support a lack of accountability. This is evidenced by the ineffectiveness of the current NMP wording to deliver sustained structural reform that results in significant impact on health outcomes for Aboriginal and Torres Strait Islander people, as cited above.

The poor coordination of medicines access and safety information and absence of a national strategy for Aboriginal and Torres Strait Islander medicines information, should be addressed in the NMP. This is consistent with the CTG Priority Reform areas related to shared decision-making and access to data. Such governance may inform other system-level activities, such as HTA reform and pharmacovigilance strategies. Governance may also provide performance measures and evaluation strategies that meet perspectives of stakeholders more effectively.

Current methods for measuring Australia's medicines policy impact for Aboriginal and Torres Strait Islander people are disparate, not focused on outcomes, under-resourced and uncoordinated. Some current measures that highlight these concerns include PBS data, 7CPA Key Performance Measures and ABS statistics. A strategic approach is needed to bring together all elements of data to drive coordinated policy change at a Commonwealth and systems-level. This approach should be led through the principal Aboriginal and Torres Strait Islander medicines advisory body.

Understanding and documenting how the NMP has influenced key national medicines-related policy is important. For example, how has the NMP has influenced programs that support increasing pharmacist workforce and QUM activity, such as the Workforce Incentive Program, The Pharmaceutical Reform Agreements and MBS items related to medicines?

> **Recommendation 5:**
> A comprehensive and sustained NMP implementation, communication, monitoring and evaluation strategy/s is required for the life of the policy. This strategy must endeavour to focus on health outcomes.

This must be adequately resourced and may include one or successive implementation plans, oversight committee/s and explicit monitoring and evaluation strategies. All monitoring and evaluation activities must apply an equity lens to ensure Aboriginal and Torres Strait Islander people are at least equally benefiting from the policy, this may be overseen by the Aboriginal and Torres Strait Islander medicines advisory body. Indicators must also be comprehensible to all stakeholders to ensure adequate understanding and engagement across the health sector, including consumers. Organisations and companies commissioned to provide oversight, implementation, evaluation and communication of NMP-related activities should be independent and unbiased to stakeholder and government perspectives.

Good governance engenders public and stakeholder trust in the policy, example of how this may be achieved include:[12]

- Improving transparency for medicines risks and benefits through ensuring availability of consumer-based medicines information (including for complementary medicines)
- Improved transparency for out-of-pocket costs for medicines
- Transparency and consistency regarding access to medicines across hospitals
  Appropriate consumer protections for rapid market entry medicines
- Increased accountability for medicines sponsors to provide safety data
- Consistent reporting of conflicts of interest of NMP partners

Quality use of medicines

A greater consideration of a comprehensive *health systems* approach is required within the NMP. This is only briefly referenced in the Discussion Paper as a priority. For example, the five WHO dimensions to medication adherence go well beyond "health literacy" that is referenced in the Discussion Paper, and includes socioeconomic factors, patient-related factors, therapy-related factors, clinical condition-related factors and healthcare system-related factors.[13] More specific reference to the dimensions of adherence within the NMP may then be reflected in monitoring, evaluation and indicators.

> **Recommendation 6:**
> The NMP should take a greater health systems approach and make more specific reference to the multiple and validated dimensions of adherence available in the global health literature.

The Review of Pharmacy Remuneration and Regulation (September 2017) made several recommendations in relation to improved QUM for Aboriginal and Torres Strait Islander people. While the Australian Government has partially addressed some of these recommendations, there are some strategies recommended by this review which have not been addressed, despite ongoing data indicating health and medicines use disparity.

Failure to address these issues has ultimately meant that partners' commitments under the NMP to ensure that all "Australian consumers and health practitioners should have timely access to accurate information and education about medicines and their use" has not been met.

For example, there has been inadequate response from governments in supporting an ACCHO-embedded pharmacy workforce, ACCHO pharmacy ownership and medicines labelling support in remote communities. The current wording in the NMP has not had a tangible impact on these priorities for the Aboriginal and Torres Strait Islander health sector.

> **Recommendation 7:**
> The NMP should make more specific reference to both QUM and pharmacist services for Aboriginal and Torres Strait Islander people, in consideration of relevant national reviews and literature.

The NMP must support QUM across the whole lifecycle of a medication. Understandably industry tends to focus on new medicines with a crowded marketplace focusing on new medicines and emerging therapies, often to the detriment of equally effective older cheaper medicines.

Equity

The NMP commits all partners to consider that the quality, safety and efficacy of medicines available in Australia which "*should be equal to that of comparable countries".* Inherent bias within the policy and institutions of government can lead to inequitable access to medicines. Some countries are finding systems-level solutions for Indigenous peoples that Australia may consider.

A recent systematic review of Health Technology Assessment (HTA) in 24 Western and Asian countries found that 9 HTA agencies emphasised aspects of equity in relation to the fairness of allocating health resources across populations or individuals.[14] While Pharmaceutical Benefits Advisory Committee (PBAC) is identified in this cohort of 9, other agencies' approaches to equity are portrayed with greater specificity and clarity in this analysis. For example, PHARMAC guidelines in New Zealand Aotearoa are much more explicit in relation to Māori needs, compared to PBAC guidelines which do not contain specific considerations for Aboriginal and Torres Strait Islander

people. PHARMAC have a *Māori Responsiveness Strategy*[15] and PHARMAC guidelines has a section that seeks particular health needs of Māori population in relation to the intervention.[16] Conversely, the PBAC Guidelines simply reference equity as a "less-readily quantifiable factor that influences PBAC decisions" to be "re-evaluated case by case". [17] Interestingly, the Commonwealth Fund rank the equity of the New Zealand Aotearoa health system significantly higher than Australia. [18]

The Canadian Agency for Drugs and Technologies in Health (CADTH) has recently enhanced consideration of a variety of perspective in their HTAs. CADTH is implementing an advisory group that includes the perspectives of marginalised groups and those with disparately high needs. Members of the Patient and Community Advisory Committee assist in CADTH building its cultural competence, such as identifying bias and enhancing communication. They also aim to dismantle structural inequity, through consideration of the political, economic and racialised conditions that cause health disparity.[19]

NACCHO notes the recent international commentary and reforms in other high-income countries that supports greater community and consumer involvement through structural change. [20,21,22] The new internationally accepted definition of HTA developed by the International Network of Agencies for Health Technology Assessment (INAHTA) and Health Technology Assessment International (HTAi) has a greater focus on equity and capturing stakeholders' perspectives. Specifically, Note 3 of the definition notes that dimensions of value often include "ethical, social and cultural" aspects and that the overall value "may vary depending on the perspective taken" during HTA and may vary for the stakeholders involved. [23]

Our member services represent relatively small subpopulations where new drugs and emerging novel medical technologies may be particularly effective and yet their population size limits the market accessibility for sponsors. There are correspondingly low incentives to research, develop and commercialise new drugs and novel medical technologies for conditions that affect Aboriginal and Torres Strait Islander people, in particular orphan and off-patent that could be repurposed and used to treat such conditions. Through our stakeholder consultation, we feel that the approval process for new drugs and novel medical technologies for Aboriginal and Torres Strait Islander people could be made more equitable and efficient without unduly compromising the assessment of safety, quality, efficacy or cost-effectiveness. For example, the use of Real World Evidence in HTA is expanding internationally.[24]

Australia's HTA approach represents a structural bias that inherently disadvantages Aboriginal and Torres Strait Islander populations and compounds current health inequity for reasons including:

- Subpopulations can require specific 'niche' treatments, where a low volume of product produces low gross income and therefore is unattractive for pharmaceutical sponsors.
- Epidemiological and medicines data for subpopulations are often sparse or absent. Where available, they may only be relevant for a specific region, which makes generalisability and modelling difficult.
- Current PBAC guidelines allow some submission fee waivers but this is not promoted, and absent for the fee negation component. This policy is not formalised for applications for Aboriginal and Torres Strait Islander-specific PBS Submissions and not widely known in the sector.
- There is no formal agency or process representing Aboriginal and Torres Strait Islander needs for pharmaceutical HTA and no scheduled or structured way that the current *Listings on the PBS for Aboriginal and Torres Strait Islander people* is reviewed.

This bias is discordant with the international HTA definition described above and with the current NMP which 'aims to improve positive health outcomes for *all* Australians through their access to and wise use of medicines'. These cases and issues presented above illustrate one discrete medicines policy area (health technology assessment) where inequity and bias persist despite the NMP's aspiration to address this.

The word equity is applied too generally in the Terms of Reference and NMP itself, which diminishes the impact and importance of this concept.

Recommendation 8:
The focus on equity and consideration of systematic bias should be enhanced in the NMP (including specific reference to inequity for Aboriginal and Torres Strait Islander people).

Recommendation 9:
In enhancing the focus on equity, the NMP must define the elements of equity much more explicitly and in a way that reflects the practical equity challenges in Australia. This may include discussion of equity of access to services and to safe, effective and appropriately priced medicines, and may consider geography, racism and structural bias, socioeconomics, language and health literacy, amongst other dimensions of equity.

Recommendation 10:
Under a 'Challenges' section of the NMP, the inclusion of strategies to mitigate inequity in medicines access, including HTA, should be highlighted.

Cultural safety is highly important in relation to accessing healthcare and institutionalised racism and clinician bias and racism is relevant in the context of medicine.

Recommendation 11:
The specific inclusion of a reference to the importance of cultural safety should be included in the NMP Access objective.

Medicines access, supply and shortages issues

Despite the NMP's central objective to support timely access for all Australians, there are several ways in which this objective has not met the needs of Aboriginal and Torres Strait Islander people.

The Community Service Obligation (CSO) is the primary way that equitable distribution of PBS medicines can be achieved. The CSO agreement should ensure that medicine access is equitable and reliable for all patients regardless of where they are located within Australia. Funding of over $1 billion is provided to medicines wholesalers who meet the CSO standards, however delivery against the current CSO standards is not provided with adequate transparency or accountability to Aboriginal and Torres Strait Islander people and communities. Ultimately the NMP appears to have had minimal impact on the CSO and its value to Aboriginal and Torres Strait Islander people.

As local and global medicines shortages continue to challenge Australia's health system, both medicines sponsors and wholesalers must be more transparent and accountable to consumers and communities in relation to supply and shortage issues. As an illustration of this issue, many Australians have been in the unacceptable position of not having access to metformin, the first line therapy for type 2 diabetes, a disease which around 1 million Australians have.

The NMP be supportive of subsidised access to low-cost medicines, to remove barriers to access for vulnerable populations. For example, the NHMRC recommends that all pregnant Australian women take an iodine supplement, yet no product has been listed on the PBS.

This accountability should be managed by enforceable statutory and policy mechanisms from the Commonwealth government and supporting systems and bodies (i.e. TGA). This may include enhanced public supply and shortage information; specific and publicly reportable targets for timely and equitable access, especially for rural and remote areas; improved stock-out and shortage surveillance at consumer level; expanded accountability beyond the PBS framework (e.g. for private non-PBS scripts, hospital medicines); and improved clearer governance and consultation structures (e.g. through 7CPA PSCC).

It is vital that equitable access continues for older established medications once they are off patent. If these molecules are no longer profitable for industry there may need to be support for government or not for profit agencies to ensure adequate access and education to support evidence-based medication treatment in the long term.

> **Recommendation 12:**
> The NMP must be more specific and emphatic in relation to addressing medicines supply and shortage issues, to hold those in the medicines industry directly accountable to measurable consumer needs.

Medicines safety

The NMP states that there should be "an effective post-market monitoring system (for example, for adverse drug reactions), to ensure ongoing assessment of safety". While we accept these systems exist, they have failed to provide clear and useful information to Aboriginal and Torres Strait Islander people and communities. Under "Quality, safety and efficacy", NMP supports "governments working collaboratively and consistently with a view to achieving a best practice regulatory system". The NMP also states that consumers and practitioners should have "access to accurate information and education about medicines and their use".

The NMP makes a commitment that the quality, safety and efficacy of medicines should be equal to that of comparable countries. We understand that other high-income countries (such as the USA) have had requirements to evaluate medications by racial status for over 20 years. Aboriginal and Torres Strait Islander are disadvantaged in that there is no requirement in relation to evaluation or surveillance of medications in Australia. Additionally, reporting recommendations by racial status from other countries will be uninformative, given the likely very low proportion of Aboriginal and Torres Strait Islander people in data from other countries.

Drug safety in Aboriginal and Torres Strait Islander populations does not have a robust evidence base and yet the potential for harm is real.[25] [26] [27]Despite the NMP, there is a marked paucity of data on potential adverse drug reactions in the context of the considerable disparity in health of Aboriginal and Torres Strait Islander people and other Australians, which is of serious concern.[28]

In relation to the equity principle for all Australians to receive safe medicines, it is important to appreciate the health priorities and status of Aboriginal and Torres Strait Islander populations – we understand that there is no pre-market safety information for this population. To achieve equity for safety in this group an *active* post-market pharmacovigilance strategy for this population is required, not simply post-marketing pharmacovigilance for particular products, but across this whole Aboriginal and Torres Strait Islander population and potentially sub-populations, if and when the need is identified by respective communities and regions.

We are concerned that to date initiatives from ACSQHC in relation to medication safety have focused on errors to improve medication safety. It is important to appreciate that there is a difference between errors with medications use, which may lead to harms, and harms occurring with correct medication use. That is, a focus on errors, will overlook intrinsic risks that can occur with correct use of medications. This failure to proactively investigate harms will result in loss of opportunity for risk mitigation in the future, and potential for ongoing, avoidable harms.

A comprehensive healthcare program could include the assessment and management of potential adverse drug reactions, for all types of medicines (including over the counter and non-PBS medicines). One ACCHO member has suggested that all policies and guidelines promoting the quality use of medicine in the Aboriginal and Torres Strait Islander population should ideally include a robust pharmacovigilance strategy and an acknowledgement of the limitations of drug safety information for Aboriginal and Torres Strait Islander people.

> **Recommendation 13:**
> The NMP must make clearer reference to pharmacovigilance, including activity related to detecting, assessing, understanding and preventing adverse effects and other medicine-related problems for Aboriginal and Torres Strait Islander people.

Section B:

NACCHO Response to Discussion Paper and Terms of Reference Questions

Terms of Reference 1 – Proposed NMP Principles

1. *Equity*
2. *Consumer centred approach*
3. *Partnership based*
4. *Accountability and transparency*
5. *Stewardship*

Question A

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

The principles seem generally acceptable and congruent with stakeholder feedback and other Australian health policy and the detailed and enhanced consideration of equity for Aboriginal and Torres Strait Islander people is imperative. However, we note the policies referenced that informed these principles have little consideration of Aboriginal and Torres Strait Islander people. Australia's Health Technology Assessment (HTA) Framework does not refer to Aboriginal and Torres Strait Islander people. Also, there are inherent flaws in drawing from the HTA system as a reference, as this system is not working optimally for Aboriginal and Torres Strait Islander people, as discussed above. Furthermore, the National Strategy for Quality Use of Medicines has no reference to Aboriginal and Torres Strait Islander people throughout. The recommendations made under Section A above largely address these concerns.

1. Equity

Though this principle does go some way in providing more detail on how equity can be addressed, we provide further comments on specifically how equity can be influenced for Aboriginal and Torres Strait Islander people in Section A.

2. Consumer-centred

*See discussion in Section A including the recommendation that "*The NMP should support Aboriginal and Torres Strait Islander participation in leadership and oversight in all national medicines committees, organisations and agencies..."

Further, the term 'consumer' may be considered too narrow to capture all Australians' perspectives. The terminology does not capture a broader view of health and well-being that is essential for many Aboriginal and Torres Strait Islander peoples. There is a need to acknowledge that decisions often incorporate families, other community members and other cultural determinants.

Recommendation 14:
The term consumer must be expanded and discussed to allow for a more holistic and culturally appropriate definition to be captured

3. Partnership based

As referenced in the principle, we agree that NMP must facilitate establishing and maintaining active, respectful, collaborative and transparent partnerships, including specifically with Aboriginal and Torres Strait Islander people, to harness their distinct skills, priorities, experience, and knowledge. A national Aboriginal and Torres Strait Islander medicines advisory group as referenced in Section A is the best way to oversee and enact this activity. *The policy should include researchers as NMP partners to drive an evidence-based of best practice.*

State and territories administer medicines policy in hospitals and many Aboriginal and Torres Strait Islander health services across the country. The policy should reference the need for mechanisms to enhance partnerships between state and federal health departments to address significant medicines issues that may arise in this environment, such as during transitions of care. Each of these governments are signatories to the National Agreement on Closing the Gap.

Recommendation 15:
Comprehensive state and territory engagement is required throughout the NMP consultation – including with those who work directly with Aboriginal and Torres Strait Islander clients – to ensure that accountability and governance strategies in the NMP have consensus from all jurisdictions and that responsibility is captured for Australians who access care across state and Commonwealth settings.

4. Accountability and transparency

See discussion in Section A in relation to governance, implementation plan and monitoring and evaluation.

5. Stewardship

We generally agree with this principle, but consider referencing "where relevant" in conjunction with "equitable, efficient and sustainable" For example, NACCHO has limited leverage to provide stewardship over the viability of the medicines industry, however, we would support work in this area in partnership with the Commonwealth where appropriate.

Question B

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

The principles at a conceptual level are generally acceptable and are still referenced consistently by policy-makers throughout Australia (e.g. QUM definition is defined in some 7CPA resources). While newer comparable policy documents exist – such as WHO Medication Without Harm – the language and sector knowledge of the NMP may support continuation of its core themes, objectives and ideas, to ensure that the health sector and Australians more generally remain engaged and that policy momentum is not forgone.

However, the NMP objectives do set the dimensions of what consumers can expect from the policy and the NMP is somewhat focussed on the perspective of systems and government, rather than consumers. In consideration of the *consumer centricity* principle, we propose an additional specific objective could be added that involves understanding (i.e. through monitoring and evaluation) and then address medicines consumers needs and priorities. Consumers needs can be dynamic, heterogeneous and often decentralised. Without an objective to capture information related to consumers' needs and preferences and respond to these on an ongoing basis, it is possible that the policy too heavily focuses on the needs or perspective of the health sector, rather than its end users.

Objective: Access to medicines

Access to all medicines that clients and their respective health professionals choose to use is of critical importance for many Aboriginal and Torres Strait Islander communities. The NMP Review Discussion Paper references the Pharmaceutical Benefits Scheme (PBS) as the key mechanism through which this objective is achieved, however, this over-simplifies from the many ways in which ACCHOs work to ensure their clients have access to necessary medicines. There are many traditional and over-the-counter medicines used by clients of ACCHOs for which there may be barriers to access. Some community pharmacies may be unable to provide an environment where Aboriginal and Torres Strait Islander people feel culturally safe to access such medicines. A GP or pharmacist may discourage a client from using traditional medicines due to lack of knowledge or appreciation. Some non-remote ACCHOs choose to completely forgo PBS subsidy to stock large volumes of medicines at their own cost to ensure clients have access to medicines when and where appropriate.

Ultimately, the barriers and enablers to healthcare access for Aboriginal and Torres Strait Islander people are well documented and go beyond cost and remoteness. These elements of access and equity should be captured more clearly in the NMP, as referenced in Section A.

Objective: Quality, safety, and efficacy of medicines

The consumer perspective should be incorporated into this objective more clearly. For example, by outlining approaches the TGA can undertake to more directly gain intelligence from actual medicines consumers, including direct intelligence from specific populations such as Aboriginal and Torres Strait Islander people, and then respond dynamically to this information.

Objective: Quality use of medicines

Currently many programs funded by governments (e.g. 7CPA programs) do not collect and measure quality empirical information related to clinical QUM-related health *outcomes* to inform the program's effectiveness.

For example, neither the NMP nor the National Strategy for Quality Use of Medicines (NSQUM) is referenced in the 7th Community Pharmacy Agreement, where $1.2 billion dollars of Commonwealth

funds are directed towards programs than involve improving the use of medicines. The 6th building block of the NSQUM is "strategic research, evaluation and routine data collection…at all levels". The strategy goes on to say "Routine datasets must be established to assist in evaluation, including a comprehensive pharmacoepidemiological database that is patient-linked ...". Such a database that captures Aboriginal and Torres Strait Islander people's medicines use is not available. Disappointingly, the NSQUM contains no reference to Aboriginal and Torres Strait Islander people, despite the NMP reference to the need for enhanced medicines support for this population. Given the ongoing concerning indicative figures of medicines use for Aboriginal and Torres Strait Islander people as discussed in the introduction, this suggests that a refreshed approach is required. While the Drug Utilisation Subcommittee of PBAC (DUSC) role in analysing medicines use is important, it must consider Aboriginal and Torres Strait Islander leadership, participation and priorities more clearly. We note the work currently being conducted through the Australian Commission on Safety and Quality in Health Care, *Updating National Quality Use of Medicines Publications.* Furthermore, new investment in MRFF may be influenced by NMP to ensure research is more equitably directed to Aboriginal and Torres Strait Islander peoples' needs.

The current quality use of medicines framework does not address active risk mitigation in relation to medication related harms, particularly those occurring with correct use of medicines. The focus is around errors and misuse, rather than intrinsic harms that may occur with correct use. This is a missed opportunity for risk mitigation, leading to ongoing potentially preventable harm for future generations.

Nationally recognised QUM indicators need to be applied to all relevant QUM programs and measures. Industry may also choose to access such indicators for their respective programs and initiatives. QUM indicators should be incorporated into the NMP governance, implementation and evaluation activities. QUM indicators must be developed in collaboration with Aboriginal and Torres Strait Islander people.

> **Recommendation 16:**
> Nationally recognised QUM indicators and QUM monitoring and evaluation should be referenced more clearly in the NMP, for example through a national framework, this should also include specific or adapted QUM indicators developed by and for Aboriginal and Torres Islander people. Indicators should be incorporated into overall NMP governance processes.

Objective: Maintaining a responsible and viable medicines industry

We are concerned about the ambiguity of the term "industry". While there are some obvious inclusions, the definition is not clearly outlined in the NMP. For example, does this include a one-owner rural compounding pharmacy; a pharmacy banner group that has a range of propriety products; independent pharmaceutical consultants; or an ACCHO that supplies traditional medicines to clients and have intellectual property over a treatment? The availability (i.e. viability) of such medicines businesses listed above may be of high importance to some ACCHOs.

> **Recommendation 17:**
> We propose that cultural Intellectual Property (IP) of traditional Aboriginal and Torres Strait Islander medicines referenced in the section NMP where intellectual property is currently referenced in the NMP.

In consideration of the quadruple aim,[29] how can this policy support the labour market supply health professionals dealing with medicines in regional and remote, who are adequately supported. Similarly for service providers and regional health businesses, such as pharmacies.

We conceptually support NMP's statement related to the need for niche market medicines to be available, which may be supported by viable and local medicines industry.

Recommendation 18:
Clarify the definition of "industry", which may include expanding from a traditional definition, to ensure that medicines consumers' and health practitioners' commercial needs are met.

We acknowledge the Medicines Australia Code of Conduct as a standard for ethical conduct for promotion and marketing of medicines. This code is referenced consistently between parties when NACCHO works with industry representatives.

Recommendation 19:
The NMP should make reference to all actors included under the term industry being held to account under a national framework akin to the Medicines Australia Code of Conduct.

Terms of Reference 2 – Defining medicines

Question A

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?

Broadening inclusion provides assurance for consumers and practitioners that the structured principles and objectives which apply in the NMP apply to wider range of health technologies that consumers access. Australian medicines policies are perhaps more discrete and structured, compared to medical devices and immunisations. For example, combined Commonwealth and state and territory involvement in immunisation involves shared responsibility – thus holding these parties accountable to a consistent policy may provide consumers with assurance about the quality of access and services to these products.

Conversely, there is a risk that inclusion of medical devices may dilute the impact of the policy and make it less intuitive or more complex to understand. Unlike vaccines, medical devices are a much more disparate collection that might be difficult to define and monitor. An advantage of the NMP is it comprehensibility and conciseness. Devices being considered as specific therapeutic entities may confound evaluation of more complex medical intervention funding and hospital systems. However, considering device access from an equitable approach, the NMP may facilitate device's being subject to the same types of evaluation and funding scrutiny. Any changes within definition should ensure that the benefits and protections for Australians within the current policy are not forgone.

> **Recommendation 20:**
> We support the inclusion of vaccines.

> **Recommendation 21:**
> While we support some consideration of biotherapeutics and medical devices, the unintended consequences of inclusion should be thoroughly considered.

Traditional Aboriginal and Torres Strait Islander medicines, sometimes known as 'bush medicines', fundamentally reflect Aboriginal and Torres Strait Islander peoples' distinct wellbeing beliefs and cultures. The medicines' use can involve specific practices and associated activities well beyond what may be considered the administration of a pharmaceutical agent. Currently, the doctrines and considerations associated with traditional Aboriginal and Torres Strait Islander medicines are not adequately captured in the NMP.

> **Recommendation 22:**
> Medicines definition should include traditional Aboriginal and Torres Strait Islander medicines.

Question B

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 title is changed the impact, accessibility and 'brand equity' of the policy may be diminished. This is evidenced in other medicines bodies. For example, NPS has retained "MedicineWise" despite their

more recent involvement in medical tests. The clarity and utility of the document may be diluted with broader title, this may impact on accountability and the public's engagement with the policy

Recommendation 23:
The title can remain unchanged and definition and associated health activities be discussed clearly and early in the document.

.

Terms of Reference 3 – Rapidly evolving health sector

Question A

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

Specifically, regarding the *evolutionary* aspects health landscape and considering the overarching and strategic nature of the policy, the NMP does not appear to require foundational change. We provide recommendations throughout on changes needed in the NMP, which are somewhat incremental. Perhaps the omissions of governance and implementation has been most relevant to its responsiveness, rather than the reference to specific advancements in technologies or treatments.

Question B

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?

Actual and emerging changes may be referenced in general terms (especially in relation to digital, telehealth and precision medicine) without precluding unforeseen developments. Using more specific language may render terms obsolete or out of date. However, the use of very general language must be weighed against explicitness, as there is a danger that the necessary detail in accountability will be forgone if language is too general. For example, the term 'cultural and linguistically diverse' fails to capture the distinct needs of Aboriginal and Torres Strait Islander communities. Similarly, the scope of the document needs to balance inclusivity and engagement with accountability.

Consistent with the NMP theme of equity for all Australians, Aboriginal and Torres Strait Islander people should not be left behind in novel and emerging medicines-related opportunities. Aboriginal and Torres Strait Islander people are at risk of precision medicines activities not adequately considering their needs and priorities. This includes gene therapies, [30] cell therapies and tissue-engineered medicines, emerging interprofessional models of care (such as ACCHO-integrated pharmacists) and telehealth and digital technology. It is important that if such technologies and therapies are specifically referenced in the NMP, that Aboriginal and Torres Strait Islander peoples' unique perspectives, leadership and translation of these treatments is explicitly outlined.[31] [32] Specific consideration of Aboriginal and Torres Strait Islander perspectives is referenced in Australia's National Health Genomics Policy Framework under Strategic Priorities 1 and 5.

> **Recommendation 24:**
> The NMP should state that Aboriginal and Torres Strait Islander leadership and translation is required in the development and implementation of policy related to new and evolving treatment options

Health Literacy

We welcome the Discussion Paper's exploration of health literacy challenges. We note the theme's inclusion from the 2020 NMP Review Workshop. This issue is commonly raised in the Aboriginal and Torres Strait Islander health sector. For example, the limited utility of the standard CMI is reported commonly by our sector. As stated in the NMP Discussion Paper, low consumer health literacy can compound the disadvantage experienced by marginalised groups. Given the complexity of health

literacy, we support multiple, multimodal solutions that may be driven at a community level where community health literacy needs are best understood. The QUMAX and IHSPS programs are exemplar models where ACCHOs can commission QUM activities, in consideration of their local health literacy priorities. There are limited data on specific health literacy strengths and challenges for Aboriginal and Torres Strait Islander people. Therefore, given the known health disparities, more needs to be done to understand this.[33] Beyond the health benefits outlined in the NMP Discussion Paper, improving health literacy supports self-determination and autonomy for both individual consumers and communities.[34]

> **Recommendation 25:**
> The NMP should acknowledge the value of understanding and improving health literacy, and may reference strategies that support equity and community-control for Aboriginal and Torres Strait Islander people

A health systems approach is needed

We are concerned that the methods outlined in the NMP discussion paper do not adequately going to benefit Aboriginal peoples and Torres Strait islanders to be more empowered. The Discussion Paper states that "More complex treatment options suggest more effort will be needed…", however there is little explicit reference to how the NMP would influence this. Further, to merely "tailor and target communication and increase access to language and literacy sensitive health and medicines information using diverse communications channels" is insufficient. Rather, a more comprehensive health systems response is needed. For example, workforce measures such as enhanced referrals to HMR's (and better models of medication review) as well as health care reform towards integrated pharmacist models of care, including within ACCHOs. This approach needs to be part of the NMP, within the context of enhancing medication adherence. Without such reforms, the NMP is too heavily focussed on clinicians' perspectives and not on patients. The barriers to adherence are commonly condition-specific, and include treatment-based, socioeconomic, and health system barriers. Clinical students need to be trained to address medication adherence, as well as practising clinicians. This is not just about enhancing patient health literacy but should be a key competency and requires joint work with the respective peak education bodies. To ensure that there is an improved health systems response, we make the following recommendation.

> **Recommendation 26:**
> The NMP must reflect that all health care providers should be better educated about the factors that influence medication adherence, including skills-based training on how to address barriers to adherence. Consistent with Recommendation 5, this should be accompanied by health care system performance KPIs, which may include quality assurance activities.

NACCHO has discussed themes related to Equity and Sustainability; Real-World Evidence; and Drug Repurposing above and in the NACCHO HoR submission.

Other emerging issues [35,36]

Other emerging opportunities that may be relevant to Aboriginal and Torres Strait Islander people to consider incorporating specifically into NMP:

- **Digital health and technology**
    - How can equity of access be ensured? How is Aboriginal and Torres Strait Islander information and privacy governed and protected? What are the facilitators and barriers, including for Aboriginal and Torres Strait Islander people?

- **Genomic and personalised medicine**
    - How will the interface between PBAC and MSAC be managed, especially considering the already existing complexity and low awareness for consumers? How are legal and ethical issues and communications activities overseen for Aboriginal and Torres Strait Islander people? How do we ensure the opportunities and benefits are balanced against the risks for vulnerable cohorts?
- **Globalisation and Accelerated Access**
    - How can Real World Evidence collection and use occur for Aboriginal and Torres Strait Islander people? How can Aboriginal and Torres Strait Islander people be proactive in accelerating access?
- **Transitions of care**
    - Given the known challenges in relation to tertiary care and transitions to primary care,[37] the NMP may reference the importance of equitable continuity of care between settings for all Australians. Interactions between the federal PBS and state-based hospital systems needs to be improved to reduce risks at transitions of care and to create equitable access to medicines across the country.
- **Innovative funding models**
    - How can the NMP explicitly reference novel funding models that improve access to medicines for Aboriginal and Torres Strait Islander people?
- **Medicines stewardship issues**
    - How can NMP more clearly reference the emerging medicines stewardship activities for opioids, antibiotics and other medicines? What specifically should be discussed in the NMP in relation to Aboriginal and Torres Strait Islander people's distinct needs with these issues?
- **Polypharmacy**
    - How can the risks for Aboriginal and Torres Strait Islander people associated with taking many medicines often required to treat one or more chronic conditions be addressed at a population level without negatively impacting on adherence and persistence?
- **High-risk medicines**
    - How can approaches for managing high-risk medicines be translated appropriately in Aboriginal and Torres Strait Islander health settings, in all geographical locations.
- **Pricing policies**
    - What is the impact of affordability and access for Aboriginal and Torres Strait Islander people?
- **Biosimilars**
    - What relevant information and support is available for Aboriginal and Torres Strait Islander people?

Terms of Reference 4 – Consumer centricity

Question A

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

We explain how Aboriginal and Torres Strait Islander communities and consumers voices can be more enshrined within the NMP in Section A of this submission.

The Australian Charter of Healthcare Rights references the right for consumers to have their culture, identity, beliefs and choices recognised and respected. We appreciate appointment of consumers on committee cited in Discussion Paper, but note that these members do not have cultural authority to guide "culturally appropriate health environments" for Aboriginal and Torres Strait Islander people.

Aboriginal and Torres Strait Islander peoples' health paradigms, models of care, needs and priorities are distinct from mainstream Australian healthcare. Consumer and community engagement processes must explicitly incorporate Aboriginal and Torres Strait Islander voices, otherwise inequity will persist.

Any section of the NMP focused on consumers, needs to make substantive reference of Australia's First Nations peoples.

Terms of Reference 5 – Governance, communications, implementation and evaluation

Question A

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

NACCHO notes the activity related to governance and implementation that occurred in the several years after the NMP was created, including activity through the Australian Pharmaceutical Advisory Council (APAC) and a committee responsible for establishing PBS listings specifically for Aboriginal and Torres Strait Islander people. These committees brought about true structural reform, however such national leadership for medicines has effectively been abandoned.

As we reference in Section A, a sustained approach to national medicines governance should be convened. This governance should be accompanied by a robust monitoring and evaluation program, including a performance indicator framework, and effective ongoing communication. A specific Aboriginal and Torres Strait Islander advisory group is needed, who may define strategies, reform priorities and indicators relevant to Aboriginal and Torres Strait Islander people. Without such governance there is significant risk that the current inequity will perpetuate.

Question B

How can communication about the NMP be enhanced or improved?

We acknowledge a lack of engagement with the NMP from medicines consumers and the sector. Despite the advantage of its conciseness, health literacy, language and cultural considerations may influence the utility and interaction by communities and consumers with such a policy. We ask the review committee to consider what is a reasonable and necessary level of engagement from a consumer for the policy to be effective. Ultimately, regardless of the community or consumer policy knowledge, the NMP should aspire for the consumer experience to be seamless through their care journey, with the ability to receive the medicines and associated services when and where they need them, in an appropriate and culturally safe way. From this perspective, consumers' knowledge of the details of the NMP is secondary. Communication and NMP awareness strategies, may include case studies, detailed online information and reporting, NMP materials translated into appropriate level/s and types of language/s.

Recommendation 27:
Implementation of the refreshed NMP should include a suite of translated materials, which may include plain language summaries and specific reference to what consumers and communities can expect the NMP to deliver and what to do if they are concerned that this is not happening. This may include case studies.

Recommendation 28:
Measurement and evaluation of communication activity should be incorporated into indicators and governance of the NMP

Question C

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

Recommendation 29:
In continuation from the recommendations above, Aboriginal and Torres Strait Islander peak bodies and the relevant Aboriginal and Torres Strait Islander advisory group/s should be involved in communication strategies.

Recommendation 30:
The NMP may reference the need for associated guidelines and policies to link back to the NMP (e.g. 7CPA).

Terms of Reference 6 – Accountability and conflicts of interest

NACCHO has provided commentary throughout Section A regarding the critical importance of partnership, leadership and governance with Aboriginal and Torres Strait Islander people.

Question A

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

> **Recommendation 31:**
> The NMP may more specifically define partners and sub-groups of partners, such as 'effector arms' of the NMP, which may include TGA, NPS MedicinesWise, Jurisdictional Therapeutics Advisory Groups, PBAC and more. In further defining sub-groups, governance, monitoring and evaluation activities may be more clearly defined (in the NMP or subsequent implementation plans).

> **Recommendation 32:**
> Literature-based measures of partnerships should be incorporated into the indicators, monitoring and evaluation of the NMP.

Question B

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?

The way partners defined in the NMP appears to balance specificity with inclusivity and is generally acceptable. The continued inclusion of "Aboriginal and Torres Strait Islander people" is essential.

Question C

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

Within the Priority Reforms of National Agreement on Closing The Gap, NACCHO supports accountability and responsibility of both governments and partnerships themselves. By the NMP making reference to national Aboriginal and Torres Strait Islander agreements and relevant policies (as per Section A), accountability will be incorporated. NMP reference to a specific national Aboriginal and Torres Strait Islander medicines advisory body, could further embed accountability and partnerships.

> **Recommendation 33:**
> The NMP indicators should have explicit metrics associated with accountability and partnership, which may be based on appropriate Australian and international literature.

Question D

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

Standard and transparent conflicts of interest processes are required across HTA and industry activities. We support HTA meetings being open to public, as is conducted in the United Kingdom. The NMP may refer to an overall conflicts of interest charter, developed through a governance group. Such a charter must have specific to Aboriginal and Torres Strait Islander peoples needs and priorities. The NMP should provide guidance to mitigate the effectiveness of patient advocacy groups with undisclosed interests and/or financial support representing low-evidence or low-value treatments in influencing the objective and rigorous medicines regulatory and assessment processes.

References

[1] Panaretto, K. S., Wenitong, M., Button, S., & Ring, I. T. (2014). Aboriginal community controlled health services: leading the way in primary care. *Medical Journal of Australia*, *200*(11), 649-652.

[2] Campbell, M. A., Hunt, J., Scrimgeour, D. J., Davey, M., & Jones, V. (2017). Contribution of Aboriginal Community-Controlled Health Services to improving Aboriginal health: an evidence review. Australian Health Review, 42(2), 218-226.

[3] Davy, C., Harfield, S., McArthur, A., Munn, Z., & Brown, A. (2016). Access to primary health care services for Indigenous peoples: A framework synthesis. *International Journal for Equity in Health*, *15*(1), 1-9.

[4] Finlay, S., & Wenitong, M. (2020). Aboriginal Community Controlled Health Organisations are taking a leading role in COVID-19 health communication. Australian and New Zealand journal of public health.

[5] Pettit, S., Simpson, P., Jones, J., Williams, M., Islam, M. M., Parkinson, A., ... & Butler, T. (2019). Holistic primary health care for Aboriginal and Torres Strait Islander prisoners: exploring the role of Aboriginal Community Controlled Health Organisations. *Australian and New Zealand journal of public health*, *43*(6), 538-543.

[6] Bourke, C. J., Marrie, H., & Marrie, A. (2018). Transforming institutional racism at an Australian hospital. *Australian Health Review*, *43*(6), 611-618.

[7] Durey, A., Bessarab, D., & Slack-Smith, L. (2016). The mouth as a site of structural inequalities; the experience of Aboriginal Australians. *Community Dent Health*, *33*(2), 161-3.

[8] Australian Institute of Health and Welfare 2018. Australia's health 2018: in brief. Cat. no. AUS 222. Canberra: AIHW.

[9] Bond, Chelsea J., and David Singh. "More than a refresh required for closing the gap of Indigenous health inequality." Medical Journal of Australia 212.5 (2020): 198-199.

[10] Australian Institute of Health and Welfare 2020. Aboriginal and Torres Strait Islander Health Performance Framework 2020 summary report. Cat. no. IHPF 2. Canberra: AIHW.

[11] Schneider, Eric C., et al. Mirror Mirror 2017. New York: Commonwealth Fund, 2017.

[12] Adapted from NPS MedicineWise policy, 2021

[13] De Geest, S. and Sabaté, E., 2003. Adherence to long-term therapies: evidence for action. European Journal of Cardiovascular Nursing, 2(4), pp.323-323.

[14] Wang, Yitong, et al. "Which Criteria are Considered and How are They Evaluated in Health Technology Assessments? A Review of Methodological Guidelines Used in Western and Asian Countries." *Applied Health Economics and Health Policy* (2021): 1-24.

[15] Te Whaioranga 2013 – 2023, Pharmaceutical Management Agency, Māori Responsiveness Strategy. Accessed https://pharmac.govt.nz/assets/te-whaioranga-iii-strategy-2013-2023.pdf

[16] New Zealand Aotearoa Pharmaceutical Management Agency. Guidelines for Funding Applications to PHARMAC. 2017. Accessed https://pharmac.govt.nz/assets/guidelines-for-funding-applications-2017-09.pdf

[17] Commonwealth of Australia, Department of Health. Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee. Version 5.0, 2016

[18] Schneider, Eric C., et al. Mirror Mirror 2017. New York: Commonwealth Fund, 2017.

[19] Berglas S, Vautour N, Bell D (2021). Creating a patient and community advisory committee at the Canadian Agency for Drugs and Technologies in Health. International Journal of Technology Assessment in Health Care 1–4. https://doi.org/10.1017/S0266462320002251

[20] Berglas, Sarah, Nadine Vautour, and Daryl Bell. "Creating a patient and community advisory committee at the Canadian Agency for Drugs and Technologies in Health." International Journal of Technology Assessment in Health Care (2021): 1-4.

[21] Viswambaram, A., et al. "Consumer Comments in Health Technology Assessment in Australia: How Common and Influential Are They?." Value in Health 20.9 (2017): A653-A654.

[22] Hamilton K. et al. Presented at ISPOR 19th Annual European Congress, 29 October–2 November 2016. Vienna, Austria. PHP6;

[23] O'Rourke, B., Oortwijn, W., & Schuller, T. (2020). The new definition of health technology assessment: A milestone in international collaboration. International Journal of Technology Assessment in Health Care, 36(3), 187-190. doi:10.1017/S0266462320000215

[24] Klonoff, D. C. (2020). The new FDA real-world evidence program to support development of drugs and biologics. Journal of diabetes science and technology, 14(2), 345-349.

[25] Somogyi A, Barratt D, Phillips EJ, Moore K, Ilyas F, Gabb GM. High and variable population prevalence of HLA-B*56:02 in Indigenous Australians and relation to phenytoin-associated DRESS. British Journal of Clinical Pharmacology. 2019;85(10): DOI:10.1111/bcp.14032

[26] Mahajan H, Thynne T, Gabb GM, Poh EW. Drug safety in Aboriginal Australians: three cases of angiotensin-converting enzyme inhibitor angioedema. Internal Medicine Journal 2015;45(2):231-233

[27] Gabb GM, Vitry A, Limaye V, Alhami G. Serious statin associated myotoxicity and rhabdomyolysis in Aboriginal and Torres Strait Islanders: a case series. Internal Medicine Journal 2013;43(9):987-992

[28] Thynne T, Gabb GM. Therapeutic drugs safety for Indigenous Australians: how do we close the gap? Med J Aust 2016;204(1):16-17

[29] Sikka, R., Morath, J. M., & Leape, L. (2015). The quadruple aim: care, health, cost and meaning in work.

[30] Nagaraj, S., & Toombs, M. The Gene-Drug Duality: Exploring the Pharmacogenomics of Indigenous Populations. 20 September 2021. *Frontiers in Genetics*, 1512.
[31] Huebner, S., Hermes, A., & Easteal, S. (2020). The Practice of Engaging Aboriginal and Torres Strait Islander Communities in Genome Research. In Indigenous Research Ethics: Claiming Research Sovereignty Beyond Deficit and the Colonial Legacy. Emerald Publishing Limited.
[32] Prictor, M., Huebner, S., Teare, H. J., Burchill, L., & Kaye, J. (2020). Australian aboriginal and torres strait islander collections of genetic heritage: the legal, ethical and practical considerations of a dynamic consent approach to decision making. Journal of Law, Medicine & Ethics, 48(1), 205-217.
[33] Nash S, Arora A. Interventions to improve health literacy among Aboriginal and Torres Strait Islander Peoples: a systematic review. BMC public health. 2021 Dec;21(1):1-5.
[34] Nash S, Arora A. Interventions to improve health literacy among Aboriginal and Torres Strait Islander Peoples: a systematic review. BMC public health. 2021 Dec;21(1):1-5.
[35] Sansom, L. Australia's National Medicines Policy-time for a refresh? Presented Jan 20, 2020. Australian Department of Health, 2020.
[36] WHO Global Patient Safety Challenge. "Medication without harm." World Health Organization (2017).
[37] Bar-Zeev, S. J., Barclay, L., Farrington, C., & Kildea, S. (2012). From hospital to home: the quality and safety of a postnatal discharge system used for remote dwelling Aboriginal mothers and infants in the top end of Australia. Midwifery, 28(3), 366-373.