PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR CONSIDERATION BY DIRECTOR OF OPERATIONS UNDER DELEGATED AUTHORITY

To: Director of Operations

From: Manager Pharmaceutical Funding

Date: 23 March 2022

Influenza vaccine widened access for Māori and Pacific peoples 55-64 years of age

Recommendations

It is recommended that having regard to the decision-making framework set out in PHARMAC's Operating Policies and Procedures you exercise your delegated authority and:

resolve to amend the eligibility criteria for Influenza vaccine inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) (Afluria Quad) in Section I of the Pharmaceutical Schedule from 1 April 2022 (additions in bold):

A. INFLUENZA VACCINE – people 3 years and over
is available each year for patients aged 3 years and over who meet the following criteria, as set by Pharmac:
- a. all people 65 years of age and over; or
- b. **people 55 to 64 years of age (inclusive) who are Māori or any Pacific ethnicity; or**
- c. people under 65 years of age who:
  - i. have any of the following cardiovascular diseases:
    - a. ischaemic heart disease, or
    - b. congestive heart failure, or
    - c. rheumatic heart disease, or
    - d. congenital heart disease, or
    - e. cerebrovascular disease; or
  - ii. have either of the following chronic respiratory diseases:
    - a. asthma, if on a regular preventative therapy, or
    - b. other chronic respiratory disease with impaired lung function; or
  - iii. have diabetes; or
  - iv. have chronic renal disease; or
  - v. have any cancer, excluding basal and squamous skin cancers if not invasive; or
  - vi. have any of the following other conditions:
    - a. autoimmune disease, or
    - b. immune suppression or immune deficiency, or
    - c. HIV, or
    - d. transplant recipients, or
    - e. neuromuscular and CNS diseases/disorders, or
    - f. haemoglobinopathies, or
    - g. are children on long term aspirin, or
    - h. have a cochlear implant, or

i. errors of metabolism at risk of major metabolic decompensation, or
j. pre and post splenectomy, or
k. down syndrome, or

vii. are pregnant; or

d. children 3 and 4 years of age (inclusive) who have been hospitalised for respiratory illness or have a history of significant respiratory illness;

Unless meeting the criteria set out above, the following conditions are excluded from funding:

a asthma not requiring regular preventative therapy,
b hypertension and/or dyslipidaemia without evidence of end-organ disease.

B. Contractors will be entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with their DHB for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

C. Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

resolve to amend the restriction criteria for Influenza vaccine inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) (Afluria Quad) in Part II of Section H of the Pharmaceutical Schedule from 1 April 2022 (additions in bold):

Restricted
Initiation - People of Māori or any Pacific ethnicity
People 55 to 64 years of age (inclusive) who are Māori or any Pacific ethnicity.

resolve that consultation on this proposal was appropriate, and no further consultation is required.

SUMMARY OF PHARMACEUTICAL – INFLUENZA VACCINE						
Brand name		Afluria Quad		**Chemical name**		Influenza vaccine
Therapeutic Group		Vaccines		**Presentation**		Inj 60 mcg in 0.5 ml syringe
Supplier		Sanofi Pasteur		**Pharmaceutical type**		Restriction change
MoH Restriction		Prescription medicine		**Application date**		March 2022
Market data		**YE 30 June 2022**	**YE 30 June 2023**	**YE 30 June 2024**	**YE 30 June 2025**	**YE 30 June 2026**
Number of patients		39,000	0	0	0	**0**
Number of Māori / Pacific peoples		39,000	0	0	0	**0**
Community Pharmaceutical Expenditure	Subsidy (gross)		Section 9 2 b (ii) [redacted]			
	Net cost of community pharmaceuticals					
	Net present value (NPV)					
TOTAL – Combined Pharmaceutical Budget	Net cost to CPB					
	Net present value					
Other DHB costs	Distribution costs					
	Other costs to DHBs					
	Net other costs to DHBs					
	Net present value (NPV)					
TOTAL	Total cost to DHBs					
	Net present value (NPV)					

Notes:
1. Number of patients = number of new patients in each financial year.
2. Subsidy (gross) = forecast of all spending at the current subsidy.
   Net cost to CPB = forecast of change in total spending on pharmaceuticals listed in the Schedule compared with status quo. Costs would be recovered from the Covid-19 Response and Recovery Fund.
3. Total cost to DHBs = net cost to the Schedule plus net cost to DHBs. Costs would be recovered from the Covid-19 Response and Recovery Fund.
4. All costs are expressed ex-manufacturer, ex-GST.
5. NPV is calculated over 5 years using an annual discount rate of 8%.
6. Calculations are in A1577079.

Why proposal should be considered by the Director of Operations under Delegated Authority

The proposal involves a Schedule change that has an estimated Financial Impact (NPV) of less than $[redacted] and:

- will not result in the Pharmaceutical budget or its future funding path being exceeded;
- is not inconsistent with previous Board decisions; and
- is not considered contentious by PHARMAC staff.

Background and Analysis

Background

- Border restrictions and other COVID-19 related public health measures have resulted in very little influenza virus circulating in the community for the last two years. Our clinical advisors have told us that the lack of community exposure to the influenza virus is likely to have reduced the natural level immunity in the New Zealand population. With the opening of borders we are aware that this is likely to increase the risk of severe illness from influenza for people at high risk.

- The Ministry of Health has been working with Pharmac since September 2021 to provide options to the Social Welfare Committee (SWC) of Cabinet for addressing the increased risks for the 2022 influenza season. While a number of options have been considered, Pharmac and the Ministry share the collective view that the key activity should be focused on improving uptake among those already eligible for funded influenza vaccine, the most likley programme to improve access equity for influenza vaccine. To achieve this, The Ministry of Health is proposing to utilise learnings from the COVID-19 and Māori Influenza and Measles Vaccination Programme (MIMVP) to ensure there is a strong equity focus for the implementation of the influenza programme.

- One of the options considered for inclusion in the options to Ministers, is widened access for Māori and Pacific peoples from 55 to 64 years of age. Pharmac indicated to the Ministry that it could support this widening of access without the need to secure additional supplies of vaccine. This option would be complementary with the focus on increasing coverage of already eligible populations.

- Māori and Pacific populations have a younger age distribution than other population groups and high incidence of comorbidities. Clinical advice from the Immunisation Advisory Committee noted that Māori and Pacific Peoples are at increased risk from seasonal influenza. Influenza vaccination uptake in Māori and Pacific peoples is lower than the wider population. Widening access from an earlier age would increase coverage in Māori and Pacific Peoples as a greater proportion of the population would be able to access funded vaccination without the need to access healthcare services to confirm eligibility under comorbidity related criteria.

Proposal

- This proposal is to widen access to influenza vaccine from 1 April 2022 for Māori and Pacific Peoples from 55 to 64 years of age (inclusive).

- If approved, this widened access is expected to reduce the impact of influenza to high-risk populations during the COVID-19 pandemic.
- Widened access would only be available for the 2022 influenza season and continued funding for future seasons would be assessed as a separate proposal.
- As this proposal addresses health needs related to COVID-19, the costs would be recovered from the COVID-19 Response and Recovery Fund (CRRF).

Agreement (if applicable)

- There is an existing agreement with Seqirus for the supply of influenza vaccine, dated 9 May 2019. The agreement resulted from a Request for Proposals (RFP) dated 20 November 2018. Seqirus has been informed of the proposal as part of the consultation process and has confirmed it would be able to meet the increased demand as a result of this proposal.

Health Need

- Influenza can be a serious illness that is sometimes fatal. Infection with the influenza virus may lead to a stay in hospital for people of any age, but particularly if you are elderly or have an ongoing medical condition. Influenza can worsen existing medical conditions such as asthma or diabetes.
- Influenza vaccine is funded each year for a range of people, including those 65 years and older, in pregnancy, and for people with medical conditions such as heart disease, respiratory conditions, diabetes, renal disease, and autoimmune diseases. Over 1.4 million people are usually vaccinated annually (funded and privately purchased).
- Afluria Quad and Afluria Quad Junior are the only funded influenza vaccines for the 2022 season and this proposal relates to only the Afluria Quad vaccine for people 3 years of age and over. It is a quadrivalent vaccine, which means it protects against four strains of influenza virus. For the 2022 season, the strains included are: A/Victoria, A/Darwin, B/Austria and B/Phuket.
- As noted above, influenza vaccine is currently funded for all people 65 years of age and older, however, vaccination rates are much lower for Māori and Pacific peoples compared to the wider non-Māori, non-Pacific population. Māori and Pacific peoples have a younger age distribution than other population groups and a high incidence of comorbidities.
- Many Māori and Pacific peoples from 55 to 64 years of age may already be eligible for funded influenza vaccine if they have other serious health conditions such as asthma, diabetes, or heart disease. Earlier access at a younger age would mean that more Māori and Pacific peoples could benefit from funded influenza vaccination as fewer reach the age of 65 years than other population groups.
- Introducing aged-based criteria with earlier access for Māori and Pacific peoples would also reduce health system barriers to accessing funded influenza vaccination as eligible people would not need to have already accessed health services to receive a diagnosis of a qualifying condition.
- We are proposing to introduce aged-based criteria with earlier access for Māori and Pacific peoples as a proactive move to address medicines access equity for population groups who are at high risk of poor outcomes such as hospitalisation or death from influenza, where there is already evidence of inequities in access to

already funded influenza vaccine.

Health Benefit

- Influenza vaccine is funded each year for a range of people, including those 65 years and older, in pregnancy, and for people with medical conditions such as heart disease, respiratory conditions, diabetes, renal disease, and autoimmune diseases. Over 1.4 million people are usually vaccinated annually (funded and privately purchased).
- The Afluria Quad and Afluria Quad Junior are the only funded influenza vaccines for the 2022 season and this proposal relates to only the Afluria Quad vaccine. It is a quadrivalent vaccine, protecting against four strains of influenza virus. For the 2022 season, the strains included are: A/Victoria, A/Darwin, B/Austria and B/Phuket.

Immunisation Advisory Committee View

- The Immunisation Subcommittee considered influenza vaccine for Māori and Pacific peoples from 55 years of age in 2018. At the time it recommended it be declined as it considered increasing coverage would be more effective than targeting by ethnicity.

- In March 2022, the Immunisation Advisory Committee provided clinical advice by email about options for widened access to influenza vaccine. Members considered that there is likley to be low immunity to influenza in the community due to border restrictions and other public health measures to manage COVID-19. With the opening of borders we are aware that this is likely to increase the risk of severe illness from influenza for people at high risk.

- Overall, while Members agreed that Māori and Pacific people 55 years of age and over are at high risk of poor outcomes from influenza, they considered that open access for the highest risk age groups, such as children under 5 years of age and people over 55 years of age would be their preferred approach.

- Members noted that the Committee had previously considered earlier access for Māori and Pacific peoples from 55 years of age. Members considered that the Committee should review more recent evidence about the age at which risks of hospitalisations and mortality begin to increase for Māori and Pacific peoples as members considered that data on the burden of disease for Māori and Pacific peoples suggests influenza is associated with increased hospitalisations from 50 years of age. Members also noted that there is good evidence that cell mediated immunity, an important factor for protection against influenza, starts to wane from 50 years of age.

- Members highlighted that there are also other high needs groups that were not included in the options under discussion, such as people with serious mental health or addiction issues. Members also noted that funding for a range of additional groups would be desirable, such as: all children under 5 years of age, school aged children, all people from 55-64 years of age, Māori and Pacific peoples aged 50-64 years, and Community Services Card holders.

- Members considered that COVID-19 has had a major impact on the workload of General Practitioners, pharmacists and other organisations that are involved in providing vaccination services. Members considered that this proposed change would be challenging for vaccination providers to implement a targeted recall

programme to reach the right people.

Full details of the advice provided is available from fA312477.

Advisor Conflicts of Interest

No relevant conflicts of interest have been declared by any of the clinical advisors who contributed to the above advice.

- Pharmac has been working with the Ministry of Health over recent months to evaluate a number of options for potential widened access to influenza vaccine. Pharmac staff consider that, at this late stage before the start of the season, it would not be possible to increase vaccine supply to any significant extent to allow for widened access to larger groups outlined in clinical advice. In particular, supply of the paediatric vaccine for children under 3 years of age is very constrained. Larger groups include all children under 5 years of age, school aged children, all people from 50-64 years of age, and Community Services Card holders.

- In a recent Health Report (HR20220324) the Ministry supported widening access to Māori and Pacific people from 55 to 64 years of age. The Ministry noted that Māori and Pacific peoples are over-represented in poorer quality and overcrowded housing, leaving them at higher risk of influenza infection alongside COVID-19. Hospitalisations related to influenza affects Māori and Pacific peoples at a younger age compared to other ethnic groups. The Ministry's CVTAG advisory group recommended that specific consideration be given to promoting and improving vaccine access to groups that have experienced disproportionate COVID-19 and influenza morbidity and mortality, as well as those with barriers to routine health care, especially for Māori and Pacific peoples.

- In response to Immunisation Advisory Group concerns about the ability of the sector to implement an additional targeted campaign for 2022, staff sought comment from the Ministry of Health Immunisation Implementation Team, which manages the implementation of immunisation programmes. The Ministry advised that it has a number of workstreams in progress that would support the traditional workforce for influenza vaccination. These programmes include:

    - expanding the influenza vaccinator workforce to include other health workers
    - DHBs considering how to leverage systems and processes for COVID-19 vaccine to support influenza vaccinations
    - use of the National Immunisation Solution (NIS) for the 2022 influenza season, improving workflows for general practice

- Staff acknowledge that this proposal, if approved, could put additional strain on vaccination providers when they are already busy administering COVID-19 vaccine and managing many COVID-19 cases in their communities. While we acknowledge this issue, we consider the number of additional people who would be eligible under the new criteria is relatively small, so many providers would not have a large number of additional eligible people as a result. Staff consider that this proposal would reduce health system access barriers for groups who are at higher risk of poor outcomes from influenza, such as hospitalisation and death.

Suitability

- Influenza vaccine (Afluria Quad) has been approved by Medsafe for the prevention of influenza caused by Influenza Virus, Types A and B contained in the vaccine. It is approved for use in people 3 years of age and older.

- Each 0.5 ml dose of the vaccine is supplied in a prefilled syringe with needle included.

Costs and Savings

- This proposal would result in an estimated cost to the CRRF of $[redacted] Section 9 2 b (ii) There would be no cost to the CPB or DHBs. The proposal only relates to the first financial year (YE 30 June 2022).
- The influenza season runs from 1 April to 31 December each year, but the vast majority of vaccine distribution and hence, budget impact, occurs from 1 April to 30 June each year. Accordingly, no costs from the 2021 season have been assumed for the second financial year (YE 30 June 2023).
- This proposal would benefit up to 39,000 newly eligible people in the first financial year (YE 30 June 2022), with likely uptake 50% of this.[1]
- The financial impact assumes 100% uptake of the proposed group. While this uptake is likely higher than might be achieved, it is difficult to estimate accurately as it is dependent on the implementation plans put in place by the Ministry of Health. The Ministry has advised us that it intends to leverage mechanisms established to target Māori and Pacific communities for COVID-19 vaccinations, so staff do not consider it unreasonable to assume a greater uptake than might otherwise be achieved.
- There are no costs or savings to the person or their whānau as part of this proposal.

Comments from Interested Parties

Section 49(a) of the New Zealand Public Health and Disability Act 2000 (the Act) requires Pharmac to consult, when it considers appropriate to do so.

Accordingly, a consultation letter was circulated on 8 March 2022. The consultation letter and all responses received by 18 March 2022 are attached as Appendix One. The consultation timeframe was shortened to ten days to allow the sector to be notified and for the Ministry of Health Sector Services to ensure vaccination claims could be processed in time for the 1 April 2022 start of the influenza season.

55 responses were received; responders included prescribers, nurses, pharmacists, DHBs, PHOs, Professional Colleges, Māori health providers, suppliers (Sanofi) and other groups/individuals.

Summaries of what Pharmac staff believe are the significant matters raised in these responses are provided in the table below. For the full response, please refer to Appendix One.

Stakeholder group	Response theme	Pharmac staff comment

[1] Nowlan et al NZMJ 2019 at https://www.immune.org.nz/age-not-just-number-synopsis-5th-new-zealand-influenza-symposium-2019; population-weighted average of 45% uptake of influenza vaccine in Māori aged 65+ and 63% in Pacific of that agegroup.

Support for the proposal		
Clinicians Colleges and Professional Groups (Pharmacy Guild, College of Nurses, ANZASW, NZHCPHN, NZMA, NZNO, RNZCGP, TSANZ) Consumers DHBs GPs Māori health organisations Mental health advocacy groups Nurses Pharmacists PHOs Regional Public Health Schools of nursing Supplier (Sanofi)	Supportive of the proposal.	We acknowledge the thoughtful responses that many people and organisations took the time to submit in support of the proposal.
Do not support ethnicity-based criteria		
GP Pharmacist Consumers	Four respondents did not support ethnicity-based criteria. The GP and consumer respondents described the proposal as racist. The pharmacist supported widening access to influenza vaccine but not based on ethnicity.	Māori and Pacific populations have a younger age distribution than other population groups and high incidence of comorbidities. Clinical advice from the Immunisation Advisory Committee noted that Māori and Pacific peoples are at increased risk from seasonal influenza. Influenza vaccination uptake in Māori and Pacific peoples is lower than the wider population. Widening access from an earlier age would increase coverage in Māori and Pacific Peoples as a greater proportion of the population would be able access funded vaccination without the need to access healthcare services to confirm eligibility under comorbidity related criteria.
Request ongoing funding of the proposed group beyond the 2022 influenza season		
Clinicians Colleges and Professional Groups (ANZASW, NZMA, TSANZ) DHBs GPs Māori Health Organisations Supplier (Sanofi)	Request ongoing funding of the proposed group beyond the 2022 season.	Widened access was proposed in the context of increased risk of poor outcomes related to reduced immunity to influenza due to public health measures to manage COVID-19. Widened access would be funded from the COVID-19 Response and Recovery Fund. Funding for future years would need to be considered from the CPB, so this would need to be considered

		against other options for investment. We intend to seek clinical advice at our next immunisation advisory group meeting on a funding proposal for ongoing funding of this population beyond the 2022 season.
Request funding for additional groups of people		
Clinicians Colleges and Professional Groups (NZHCPHN, NZMA, RNZCGP, TSANZ) Consumer GP Hapai Te Hauora Mental Health advocacy groups Nurse Pharmacist Tu Ora Compass Health Regional Public Health Supplier (Sanofi)	Requests to consider extending the proposal to cover a range of additional groups: • Children 6mths to 5 years • All people over 55 years • Māori and Pacific peoples over 45 years, and use deprivation based criteria • Māori and Pacific peoples from 50 years of age • Whānau of eligible Māori and Pacific people • All Māori to address mental health and addiction • All people with deprivation index 9 - 10 • People with serious mental health or addiction	Pharmac staff have worked with the Ministry of Health over recent months to consider a range of options for widened access to influenza vaccine. Vaccine supply quantities have already been allocated for New Zealand, and there may not be sufficient vaccine available to fund the wider groups requested. The paediatric vaccine for children from 6 - 35 months of age has particularly constrained supply so it would not be possible to fund open access for children in this age range this year. A proposal for people with serious mental health issues or addiction has received a positive recommendation from the Immunisation Subcommittee and will be ranked on the Options for Investment list. We intend to seek additional information/evidence from the responders to support their requests for wider funding to the other groups so that we can seek clinical advice at our next immunisation advisory group meeting. This would allow wider access to be considered for the flu 2023 season.
Question about how vaccinators will determine ethnicity		
Pharmacy Guild	Raised concerns, based on recent experiences with access to Rapid Antigen Testing, about possible conflict if pharmacy staff need to police the access criteria.	We acknowledge the concern that frontline staff may encounter difficult situations if they need to enforce eligibility criteria by requiring proof of ethnicity. We consider that requesting proof of ethnicity before vaccination would put an additional access barrier in place for a group that already has barriers to accessing health

		services. It is over to individual providers to satisfy themselves that the person presenting for vaccination meets the eligibility criteria. We expect that self-identification of ethnicity would be acceptable in most cases.
Sector workload		
College of Nurses NZNO ANZASW	Acknowledgement of increase workload for the sector, but the benefits outweigh the risks.	The Ministry of Health has advised us it has a number of workstreams in progress to reduce the impact on workload of the traditional vaccinator workforce.
Suggestions for successful implementation of the proposal		
NZMA NZNO Hapai Te Hauora Te Runanga o Ngati Whatua Regional Public Health	There were a number of suggestions for maximising uptake in Māori and Pacific populations, including the use of learnings from the COVID-19 vaccination programme.	We acknowledge the helpful suggestions to maximise uptake in Māori and Pacific populations. The Ministry of Health is responsible for the implementation of vaccination programmes, including the commissioning of vaccinator services, so we will share the suggestions with Ministry.
Widened vaccinator workforce		
NZNO	Noting that the Ministry is considering a non-regulated vaccinating health worker role to supplement the regulated health workforce, NZNO does not support any proposal to make this workforce permanent.	The Ministry of Health is responsible for the implementation of vaccination programmes, including the commissioning of vaccinator services, so we will share these concerns with Ministry.

Legal advisors' view

Confidential & Privileged Legal Advice from Pharmac's General Counsel

Section 9 2 h

[redacted]

PHARMAC staff have used these requirements (and, more specifically, policy guidance derived from the legal advice) as a framework to consider whether an ethnicity component in the access criteria is justified. Material addressing each of these points is included in the body of the paper and Table 1 below.

Table 1: Equity considerations

Principle *Explanatory notes*	**Pharmac view**
Evidence *There is clear evidence of a disproportionate burden of disease and equity gaps in access to existing pharmaceuticals*	Māori and Pacific populations have a younger age distribution than other population groups and high incidence of comorbidities. Clinical advice from the Immunisation Advisory Committee noted that Māori and Pacific Peoples are at increased risk from seasonal influenza. Influenza vaccination uptake in Māori and Pacific peoples is lower than the wider population, across all age groups, including those aged 65 (https://www.immune.org.nz/age-not-just-number-synopsis-5th-new-zealand-influenza-symposium-2019). In a recent Health Report (HR20220324) the Ministry noted that Māori and Pacific peoples are over-represented in poorer quality and overcrowded housing, leaving them at higher risk of influenza infection alongside COVID-19. Hospitalisations related to influenza affects Māori and Pacific peoples at a younger age compared to other ethnic groups. The Ministry's CVTAG advisory group recommended that specific consideration be given to promoting and improving vaccine access to groups that

	have experienced disproportionate COVID-19 and influenza morbidity and mortality, as well as those with barriers to routine health care, especially for Māori and Pacific peoples.
Alternative solutions *Reasonable (and similarly effective) alternative solutions that do not involve making distinctions on the basis of ethnicity have been considered*	The Immunisation Advisory Committee considered that alternative approaches such as widening access to all Community Services Card holders could be used as a proxy for socioeconomic factors. Consultation feedback generally supported wider access than proposed and also for a range of additional groups. Pharmac staff consider that, at this late stage before the start of the season, it would not be possible to increase vaccine supply to any significant extent to allow for widened access to larger groups outlined in clinical advice. All Community Services Card holders would be a large group. Similar constraints apply to the Māori and Pacific population of children aged under 5 years, another potential group requested.Pharmac staff note that the widened access proposal was to address heightened risk in the context of COVID-19 and reduced population immunity to influenza virus. The COVID-19 vaccine roll out has shown that Māori and Pacific people do not necessarily have the same level of engagement with health providers as other population groups, so targeted implementation plans are required. While at-risk Māori and Pacific peoples might be included in socioeconomic status-based criteria, the use of criteria such as Community Services Card holding would still require engagement with the system to qualify.
Effectiveness *There is a real prospect that the inclusion of ethnicity in access criteria will address the disadvantage that is identified*	Introducing aged-based criteria with earlier access for Māori and Pacific peoples would also reduce health system barriers to accessing funded influenza vaccination as eligible people would not need to have already accessed health services to receive a diagnosis of a qualifying condition.
Other contributing factors *There has been consideration of whether any proposed use of ethnicity as a criterion is wider than necessary and whether, if ethnicity is a direct proxy for other causative factors (such as socioeconomic status), it may be more effective to address those factors directly*	Māori and Pacific peoples have been particularly highlighted in clinical advice as being at risk of poorer outcomes due to reduced population immunity resulting from public health measures to manage the impact of COVID-19. Many Māori and Pacific peoples who would be included in the proposed criteria would already be eligible for funded vaccination under the current eligibility criteria for people with serious health conditions such as diabetes, chronic respiratory conditions or cardiovascular disease. However, vaccination uptake in Māori and Pacific peoples is low, so many currently eligible people do not access funded vaccine. Consequently, using socioeconomic status or other factors to identify those most at risk would not address the issue

	that Māori and Pacific peoples have barriers to accessing healthcare services.
Over and under inclusion *There is consideration of the position of those not able to access the pharmaceutical(s) in question, as well as any issues of over- or under-inclusion (where people who do not need a measure benefit simply because they belong to a targeted group, while others who may need it are denied the benefit because they belong to a group considered not to be disadvantaged)*	The proposed group considered for widened access is approximately 127,000 people, however it is estimated that 70% of this group is already eligible through existing criteria for comorbidities, so only an additional 39,000 more people would be eligible. However, current vaccination uptake in Māori and Pacific people is lower than other population groups, and unless there were better ways by the health sector to improve uptake (beyond Schedule listing) actual uptake would be expected to be half that number. The rationale for using ethnicity-based criteria in this case is because Māori and Pacific people have been identified as having barriers to accessing healthcare, which can in part be alleviated by removing the requirement to engage with the system to confirm the presence of a qualifying serious health condition.

Implementation

Section 49(b) requires PHARMAC to take measures to inform the public, groups and individuals of PHARMAC's decisions concerning the pharmaceutical schedule. Accordingly, if the Director of Operations adopts the recommendations contained in this paper PHARMAC staff will notify all suppliers, and implement the listing of these products via the usual Schedule processes.

Factors for Consideration

This paper sets out PHARMAC staff's assessment of the proposal using the Factors for Consideration in the Operating Policies and Procedures. Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. The Decision Maker is not bound to accept PHARMAC staff's assessment of the proposal under the Factors for Consideration and may attribute different significance to each of the Factors from that attributed by PHARMAC staff.

Footnotes

[1] The person receiving the medicine or medical device must be an eligible person, as set out in the Health and Disability Services Eligibility Direction 2011 under Section 32 of the New Zealand Public Health and Disability Services Act 2000.

[2] The current Māori health areas of focus are set out in PHARMAC's Te Whaioranga Strategy.

[3] Government health priorities are currently communicated to PHARMAC by the Minister of Health's Letter of Expectations.

[4] Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate).

[5] Please note PHARMAC's Factors for Consideration schematic currently does not explicitly refer to the health needs of family, whānau and wider society, but this Factor should be considered alongside those depicted in the schematic.