# Record of the Immunisation Advisory Committee Meeting held on 9 November 2023

Immunisation Advisory Committee records are published in accordance with the Terms of Reference for the Specialist Advisory Committees 2021.

**Note that this document is not necessarily a complete record of the Immunisation Advisory Committee meeting**; only the relevant portions of the meeting record relating to Immunisation Advisory Committee discussions about an application or Pharmac staff proposal that contain a recommendation are generally published.

The Immunisation Advisory Committee may:

(a) recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule and the priority it gives to such a listing;

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that Pharmac decline to list a pharmaceutical on the Pharmaceutical Schedule.

Pharmac Advisory Committees make recommendations, including priority, within their therapeutic groups of interest.

The record of this Advisory Committee meeting will be reviewed by PTAC at an upcoming meeting.

Specialist Advisory Committees and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of any one funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

# Table of Contents

## 1. Attendance

**Present**
Stephen Munn (chair)
David Murdoch
Edwin (Gary) Reynolds

Elizabeth Wilson
Karen Hoare
Lance Jennings
Nikki Turner
Osman Mansoor
Stuart Dalziel
Tony Walls

**Apologies**
Adibah Khan
Erasmus Smit
James Ussher
Michael Tatley
Sean Hanna

## 2. Summary of recommendations

| Pharmaceutical and Indication | Recommendation |
|---|---|
| • Raising upper age limit of eligibility without a time limit for the meningococcal B vaccine for children to 59 months | Positive recommendation (no formal priority) |
| • Eligibility for the meningococcal B vaccine for people aged 13-25 years be widened | Medium Priority |
| • Eligibility for meningococcal ACWY conjugate vaccine for people aged 13-25 years be widened | Medium Priority |
| • Recombinant varicella zoster virus (RVZV) vaccine for the prevention of herpes zoster in immunocompromised adults for people aged 18 years and older who are immunocompromised | High Priority |
| • Recombinant varicella zoster virus (RVZV) vaccine for the prevention of herpes zoster in immunocompromised adults for people aged 65 years and older | High Priority |
| • COVID-19 vaccination – primary vaccination continuing for anyone over 5 years and for children 6 months to 4 years 11 months with eligible comorbidities | Positive recommendation (no formal priority) |

| | |
|---|---|
| • COVID-19 vaccination – booster vaccination be funded for particular specified groups | Positive recommendation (no formal priority) |

## 3. The role of Specialist Advisory Committees and records of meetings

3.1. This meeting record of the Immunisation Advisory Committee is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) 2021 and Specialist Advisory Committees 2021.Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees and PTAC.

3.2. Conflicts of Interest are described and managed in accordance with section 6.4 of the SAC Terms of Reference.

3.3. The Immunisation Advisory Committee is a Specialist Advisory Committee of Pharmac. The Immunisation Advisory Committee and PTAC and other Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. The Immunisation Advisory Committee and other Specialist Advisory Committees may therefore, at times, make recommendations for treatments for immunisation that differ from PTAC's, including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for immunisation that differ from the Immunisation Advisory Committee's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

Pharmac considers the recommendations provided by both the Immunisation Advisory Committee and PTAC and any other relevant Specialist Advisory Committees when assessing applications for vaccines for immunisation.

## 4. Record of PTAC meeting held Thursday, August 17, 2017

4.1. The Advisory Committee noted the record of the PTAC meeting of 17-18 August 2023.

## 5. Correspondence and Matters Arising

### 5.1. Meningococcal vaccines widened access to young children and for close living situations

### Background

5.1.1. The Advisory Committee reviewed the current eligibility criteria for meningococcal vaccines and the need to consider options to widen eligibility to those vaccines.

5.1.2. The Advisory Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

### Recommendation

5.1.3. The Advisory Committee **recommended** raising the upper age limit of eligibility for the meningococcal B vaccine for children to 59 months.

5.1.4. The Advisory Committee **recommended** with **a medium priority** that eligibility for the meningococcal B vaccine for people aged 13-25 years be widened to those who are eligible for Community Services Cards, dependant rangatahi/adolescents of parents or primary caregivers eligible for a Community Services Card, or people aged 13-25 years living in NZDep quintile 5 areas.

5.1.5. The Advisory Committee considered that if eligibility for the meningococcal B vaccine was widened according to the recommendations above, then the eligibility criteria could be amended as shown below (changes in **bold** and deletions in ~~strikethrough~~).

**Meningococcal B multicomponent vaccine**

1. Any of the following:
    a. Three doses for children up to 12 months of age inclusive, for primary immunisation; or
    b. Two doses for children aged 12 to **59** months of age inclusive at first dose, for primary immunisation
    c. ~~Up to three doses (dependent on age at first dose) for a catch-up programme for children from 13 months to 59 months of age (inclusive) for primary immunisation, from 1 March 2023 to 31 August 2025; or~~
    d. Both:
        i. Person is one year of age or over; and
        ii. Any of the following:
            1. Up to two doses and a booster every five years for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post- solid organ transplant; or
            2. Up to two doses for close contracts of meningococcal disease of any group; or
            3. Up to two doses for person who has previously had meningococcal disease of any group; or
            4. Up to two doses for bone marrow transplant patients, or
            5. Up to two doses for person undergoing pre- and post-at least 28 days of planned immunosuppression*; or
    e. Both:
        i. Person is aged between 13 and 25 years (inclusive); and
        ii. ~~Both~~**Any of the following**:
            1. Two doses for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences or prisons**;** or
            2. Two doses for individuals who are currently living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences or prisons, from 1 March 2023 to 28 February 2024**; or**
            3. **Two doses for individuals living in a NZDep quintile 5 area; or**
            4. **Two doses for individuals who have, or are eligible for, a Community Services Card; or**
            5. **Two doses for individuals who are dependent rangatahi/adolescents of parents or primary caregivers who have, or are eligible, for a Community Services Card.**

5.1.6. The Advisory Committee **recommended** with a **medium priority** that eligibility for meningococcal ACWY conjugate vaccine for people aged 13-25 years be widened to those who are eligible for Community Services Cards, dependant rangatahi/adolescents of parents or primary caregivers eligible for a Community Services Card, or people aged 13-25 years living in NZDep quintile 5 areas, as shown below (changes in **bold** and deletions in ~~strikethrough~~).

**Meningococcal (groups A, C, Y and W-135 conjugate) vaccine**

1. Any of the following:
    a. Up to three doses and a booster every five years for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or

b. One dose for close contacts of meningococcal cases of any group; or
c. One dose for person who has previously had meningococcal disease of any group: or
d. A maximum of two doses for bone marrow transplant patients; or
e. A maximum of two doses for person undergoing at least 28 days of planned pre- or post-immunosuppression*; or

2. Both:
   a. Person is aged between 13 and 25 years, inclusive; and
   **b.** ~~Both~~**Any of the following:**
      i. One dose for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences, or prisons: **or**
      **ii. One dose for individuals living in a NZDep quintile 5 area; or**
      **iii. One dose for individuals who have, or are eligible for, a Community Services Card; or**
      **iv. One dose for individuals who are dependent rangatahi/adolescents of parents or primary caregivers who have, or are, eligible, for a Community Services card.**

## Discussion

5.1.7. The Committee noted:

5.1.7.1. The Immunisation Subcommittee in March 2019 and PTAC in May 2019 had recommended listing one dose of meningococcal conjugate (groups A, C, Y and W-135) vaccine with a high priority for children 1 year of age, with a one year catch up programme for children aged 1 to 4 years.

5.1.7.2. The Immunisation Subcommittee had recommended in March 2019 listing meningococcal B vaccine with a high priority for adolescents and young adults aged 13-25 years in close living situations, with a one year catch up programme. The Subcommittee had considered that adolescents and young adults in close living situations had a higher risk of meningococcal disease and that reducing nasal carriage in this group would reduce the risk.

5.1.7.3. Two doses of the 4CMenB meningococcal B four-component vaccine (4CMenB) have been funded on the National Immunisation Schedule since March 2023 for:

- Children up to 12 months of age (inclusive), with a catch-up programme for children aged 13 months to 59 months (inclusive) ending 31 August 2025.
- People aged 13-25 years (inclusive) entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, or prison, with a catch-up programme for individuals currently living in these housing situations ending 28 February 2024.

5.1.8. The Committee noted that from September 2025 only children aged up to 12 months would be eligible to commence the funded course of 4CMenB, although children who had already received at least one dose of 4CMenB would still be eligible to complete the course.

5.1.9. The Committee considered that vaccination of high-risk groups against meningococcal disease is the preferred strategy for meningococcal disease control. But as the 4CMenB vaccines over time have a limited duration of protection (waning immunity) and no indirect protection ('herd immunity'), the vaccine must be directly targeted to those at highest risk of disease and at a time when their risk is highest. In the case of the meningococcal B vaccines, there is a lack of evidence to suggest that more widespread vaccination would lead to herd immunity.

5.1.10. The Committee noted that, over the past 10 years in New Zealand, the age groups at the highest risk of developing invasive meningococcal disease (IMD) have been

children aged 0 to 12 months, and people aged 15 to 25 years. The Committee noted that within these cohorts, the risk varied by socioeconomic status (SES) and household crowding status. Either, or both, criteria could be used to target those within the highest risk age cohorts at the most elevated risk of IMD. However, there are cultural and other challenges to using crowding, compared to using SES.

5.1.11. The Committee noted an Environmental Health Intelligence New Zealand (EHINZ) fact sheet which reported that in 2019/20, the meningococcal disease notification rate among children aged 0 to 14 years living in NZDep quintile 5 areas was 10.5 per 100,000 compared to 1.4 per 100,000 for children living in the least deprived areas (rate ratio 7.4) (EHINZ. Meningococcal Disease Notifications – New Zealand. 2022).

5.1.12. The Committee noted that a lower percentage of Māori and Pacific children receive on-time immunisation by the 6 and 12-month age milestones compared to non-Māori, non-Pacific people children (Te Whatu Ora. Immunisation coverage. 2023).

5.1.13. The Committee noted inequities in access to childhood immunisations have increased for Māori in recent years. Between 2020 and 2022, the percentage point difference in childhood immunisation coverage at the 24-month milestone between Māori and New Zealand Europeans widened from 10% to 20%. During that same period, the percentage point difference in childhood immunisation coverage at the 24-month age milestone between Pacific peoples and New Zealand Europeans also widened from 3% to 11% (Immunisation Taskforce. Initial Priorities for the National Immunisation Programme in Aotearoa. 2022).

5.1.14. The Committee considered noted that lifting the upper age of eligibility without a time limit for 4CMenB to 59 months would enable more children to commence a funded course of 4CMenB, and that this would disproportionately improve access to groups of children who experience delayed access to childhood immunisations. (Children aged 12 months or more at first dose need one dose less: two vs. three)

5.1.15. The Committee considered the current eligibility criteria for 4CMenB and MenACWY, which define close-living situations as "*boarding school hostels, tertiary education halls of* residence*, military barracks, Youth Justice residences or prisons*" exclude people living in private housing, which the Canadian National Occupancy Standard (CNOS) would consider to be an overcrowded or dense living situation.

5.1.16. The Committee considered there were a number of close living situations that could be similarly appropriate to consider funding for, if access criteria were to continue to specify particular residential and occupational settings not already listed. The Committee also considered that household characteristics that contribute to a higher risk of IMD could be similarly appropriate.

5.1.16.1. The Committee considered particular close living settings (beyond those currently listed) could include those young people living in (but not limited to):

- crowded households
- residential wānanga
- Oranga Tamariki care/protection residences
- Whaikaha Disability Support Services (DSS) residences (eg young intellectually disabled)
- mental health residential programmes and facilities (Te Whatu Ora-operated, Te Whatu Ora-funded, NGOs, private)
- large student flats
- high-density households

- any other close contact / high density / high number / vulnerable resident or occupational settings.

5.1.17. The Committee noted that in New Zealand, household crowding status is defined using the Canadian National Occupancy Standard (CNOS). The Committee noted from Statistics NZ 2020 reporting of 2018 Census data that crowding rates among Māori and Pacific households were higher, relative to that of the total population, and these results are consistent with the findings from the 2013 and 2006 censuses.

5.1.18. The Committee noted a meta-analysis, which included people of all ages, reporting that people living in a crowded living space (defined as ≥5 adults/household, ≥4 household members, and sharing bedroom with 2 or more people) were at a greater risk of contracting invasive meningococcal disease compared with people living in a less crowded situation (Odds Ratio [OR] 2.78, 95% Confidence Interval [CI] 1.25-6.21). Moreover, people living in a 'high crowding index' (defined as ≥2 and ≥1.5 persons/number of bedrooms) living situation were at greater risk of contracting invasive meningococcal disease compared to people living in a low crowding index household (OR 1.67, 95% CI 1.1.6 -2.41) (Dubey et al. Int J Infect Dis. 2022:119:1-9).

5.1.19. The Committee noted that second-hand smoke exposure is a risk-factor for IMD in children and that the prevalence of this exposure was strongly associated with socioeconomic deprivation. The Committee noted another EHINZ fact sheet which reported that children aged 0 to 14 years living in NZDep quintile 5 areas were 18.1 times as likely to be exposed to second-hand smoke in the home than those in the least deprived areas. The Committee also noted evidence that young people aged 15 to 24 years, tamariki Māori and non-smoking Pacific adults were disproportionately exposed to second-hand smoke (EHINZ. Second-hand Smoke Exposure in the Home – New Zealand. 2021).

5.1.20. The Committee considered that socioeconomic status was more strongly associated with the risk of meningococcal disease than household crowding status and considered that targeting meningococcal vaccine eligibility by NZDep area or eligibility for a Community Services Card or dependant rangatahi/adolescents of parents or primary caregivers eligible for a Community Services Card would therefore appropriately target eligibility to those at the highest risk of IMD. The Committee noted that an individual's NZDep area and holding of a Community Services Card could easily be ascertained in a primary care setting.

5.1.21. The Committee considered that conceptualisations of crowding and household size may differ across cultural communities within New Zealand. The Committee considered that labelling a household as 'overcrowded' could be perceived as culturally unsafe, given many cultures value multigenerational housing or may traditionally have kinship arrangements that involve larger numbers of people. The Committee considered that targeting eligibility for meningococcal vaccines by household crowding status could unintentionally stigmatise people living in at-risk households.

5.1.22. The Committee considered also that household size can change over time, and therefore an individual's household crowding status, may change from week to week. The Committee considered that changes to household size over time may limit a prescriber/clinician's ability to determine an individual's eligibility for the meningococcal vaccine if eligibility was based on current crowding status.

5.1.23. The Committee was not aware of any evidence that the risk of meningococcal disease for individuals would be greater if the household comprised primarily people aged 13 to 25 years, but considered that this could plausibly be the case, given carriage rates for *Neisseria meningitidis* were highest in the age group aged 13 to 25 years.

## 6. Therapeutic Group and NPPA Review

### Therapeutic group distribution data and expenditure summary

6.1. The Committee noted the vaccine distribution summary data and expenditure summary for all vaccines listed on the National Immunisation Schedule or available for use in Te Whatu Ora hospitals. The Committee also noted data showing immunisation coverage data at milestone ages by ethnicity, and immunisation coverage at milestone ages by NZDep index.

6.2. The Committee noted that immunisation coverage rates at milestone ages remain lower for Māori than other populations in New Zealand and Māori children experience vaccination later than other children.

6.3. The Committee noted that the coverage figures do not include non-enrolled children, so the coverage data may not be complete. The Committee considered although the decline in immunisation coverage rates may have reached a plateau, the childhood immunisation programme must continue to focus on how to increase coverage rates. The Committee noted that the National Immunisation Programme has been putting more focus on supporting iwi and other immunisation providers, including pharmacists to help increase coverage.

*Human papillomavirus vaccine (Gardasil 9)*

6.4. The Committee noted that the 2020 nationwide COVID-19 Alert Level 4 and 3 lockdowns interrupted the school-based programme, which was associated with an extra spike in distribution occurring in June 2020. Overall distribution in 2022 was less than in 2021, and distribution up to August 2023 had been similar to the same period in 2022.

6.5. The Committee noted that the WHO has recommended and a number of international jurisdictions, including Australia, are moving to a single dose schedule. The Medsafe approved dose schedule is two or three doses. The Committee noted that there is some observational evidence supporting the use of a single dose. The Committee considered that if a one dose schedule was implemented in New Zealand, health sector resources could be used in other areas including using the savings to increase coverage or equity-specific interventions for immunisation. The Committee considered that implementing a single dose schedule could improve equity of access, where coverage is easier to achieve with a single versus 2-dose schedule, hence more people would be reported as receiving complete courses.

6.6. The Committee noted that the immunisation coverage target for HPV vaccine is 70% and noted that this is out of line with the 95% on-time targets for childhood vaccines. The Committee considered this target would be easier to achieve with a single-dose schedule, especially if the health sector savings could be allocated to immunisation equity programmes.

*Hepatitis B recombinant vaccine*

6.7. The Committee noted that Engerix B 20 mcg was listed from December 2017 and the paediatric formulation Engerix B 10 mcg was listed from November 2020. The Committee considered a preparation with 40 mcg would be preferred for some special groups such as people living with HIV or chronic kidney disease on dialysis, who are currently receiving two doses of Engerix B 20 mcg.

*Diphtheria, tetanus, pertussis and polio vaccine*

6.8. The Committee noted the distribution of Diphtheria, tetanus, pertussis and polio vaccine was lower during the 2020 March – May COVID-19 lockdown period than previous years, although distribution caught up in the second half of the year. The

Committee noted that distribution up to 31 August 2023 was tracking higher than the same time in 2021 and 2022, similar to pre-pandemic levels.

*Haemophilus influenzae type b vaccine*

6.9. The Committee noted the distribution of Haemophilus influenzae type b vaccine in 2023 was tracking consistently with previous years. The Committee noted that following the Pharmac Vaccines RFP, there will be a change in brand from GSK's Hiberix to Sanofi's Act-HIB from 1 July 2024.

*Measles, mumps and rubella vaccine*

6.10. The Committee noted the distribution and expenditure patterns for the Measles Mumps and Rubella vaccines. The Committee noted that distribution in 2023 is tracking at a similar level for the same period in 2022.

*Meningococcal conjugate vaccines*

6.11. The Committee noted that the distribution of Meningococcal ACWY vaccine to 31 August 2023 was well ahead of the full year for both 2021 and 2022 and that vaccine coverage was improving.

6.12. The Committee noted that since access to Men ACWY vaccine was widened from 1 December 2019 for people in close-living situations, increased distribution is evident in January and February of each year, likely due to uptake of the vaccine by secondary or tertiary students entering halls of residence or boarding hostels at the start of the academic year. The Committee noted that Pharmac has ranked a number of widened access proposals for Men ACWY vaccine on the Pharmac Options for Investment List.

6.13. The Committee noted that Meningococcal B vaccine (Bexsero) was funded for high-risk immunocompromised groups and close contacts of cases of any meningococcal group from July 2021. Access was further widened from March 2023 for children under 5 years of age and adolescents in close living situations.

6.14. The Committee noted that a proposal to widen access to Meningococcal B vaccine for people from 13 to 25 years of age would be considered at the meeting. The Committee noted that uptake in children under 5 years of age has been rapid.

6.15. The Committee requested that Te Whatu Ora provide more detailed information about uptake of the Meningococcal B vaccine coverage, particularly uptake by age by dose, including a 3-month rolling average.

*Pneumococcal conjugate vaccine*

6.16. The Committee noted the distribution and expenditure patterns for pneumococcal conjugate vaccines. The Committee noted that distribution of pneumococcal conjugate vaccines had reduced by a third since July 2020, which coincided with the change from a 3+1 to 2+1 dose schedule for PCV10.

6.17. The Committee noted that following an increase in invasive pneumococcal disease (IPD) notifications due to serotype 19A, PCV13 replaced PCV10 as the funded pneumococcal conjugate vaccine from 1 December 2022.

6.18. The Committee considered that there is still a rising rate of IPD caused by serotype 19A occurring in children under 5 years of age. The Committee noted that Māori and Pacific children were disproportionately represented in cases of IPD. The Committee noted that a funding application for a catch-up programme for children 1 to 5 years of age has been considered by Pharmac and is ranked on the Options for Investment List. The Committee considered that vaccine uptake in this catch-up programme would be less than 50%.

6.19. The Committee considered that herd immunity effects have been observed with PCV13 vaccine providing indirect protection (for those unvaccinated) and that child immunisation of children under 5 years of age will also provide some protection for people over 65 years of age.

6.20. The Committee strongly reiterated its view that funding a catch-up programme for children under 5 years of age is a high priority and was urgently required to reduce the burden of IPD. The Committee noted that as time progresses, fewer tamariki would be eligible for the catch-up programme as they would age out, emphasising the urgency for funding this programme to be funded.

*Pneumococcal polysaccharide vaccine*

6.21. The Committee noted that the distribution of PPV23 is significantly lower than the conjugate vaccine, since PPV23 is funded for high-risk individuals only. The Committee noted that distribution to 31 August 2023 was higher than 2021 and 2022 to the same time of year. The Committee noted that there are also private market sales of PPV23, but data was not available on the extent of private use.

*Diphtheria, tetanus and pertussis vaccine*

6.22. The Committee noted the distribution and expenditure patterns for diphtheria, tetanus and pertussis vaccine. Distribution to 31 August 2023 is tracking ahead of the same time in the previous two years.

6.23. The Committee noted that from 1 July 2019 access was widened for pertussis vaccine to include pregnant women from the second trimester of pregnancy, and parents or primary care givers of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than three days.

6.24. The Committee noted that from 1 January 2021, a clarification was made to the eligibility criteria for tetanus boosters, to reflect the current practice that the 45- and 65-year-old vaccination events are not necessarily given while a person is exactly 45 or 65 years of age, but are commonly given at any time after that birthday. The eligibility criteria now state that the tetanus booster may be given to people “from 45 years old” or “from 65 years old”.

6.25. The Committee reiterated the importance of maternal pertussis vaccination in pregnancy and considered that maternal vaccination rates are very low across the country.

*Bacillus Calmette-Guerin vaccine*

6.26. The Committee noted that there had been a long-standing shortage of BCG vaccine from June 2015 to June 2018. There had been no further supply issues, however uptake remained unpredictable and inconsistent, and dependent on fluctuating levels of inflow migration.

6.27. The Committee noted that distribution was low in 2020 and 2021, possibly related to a number of factors related to public health measures to manage the COVID-19 pandemic, including reduced immigration and reallocation of regional public health services staff to other duties.

*Diphtheria, tetanus, pertussis, polio, hepatitis B and Haemophilus influenzae type b vaccine*

6.28. The Committee noted the distribution pattern of the hexavalent vaccine has been tracking consistently with previous years, apart from a reduction in distribution during the 2020 COVID-19 lockdowns.

*Poliomyelitis vaccine*

6.29. The Committee noted that poliomyelitis vaccine distribution had increased in 2023 compared with the last two years. The Committee considered this was possibly related to the increase in international travel, since the New Zealand border was reopened following COVID-19 public health measures, which would have included countries with endemic polio or experiencing outbreaks.

*Hepatitis A vaccines*

6.30. The Committee note the distribution for hepatitis A vaccines showed occasional peaks in distribution for both paediatric and adult vaccines, which were related to localised outbreaks. An outbreak in Christchurch in January 2020 and a national outbreak from September 2022 was noted to be linked to the consumption of frozen berries.

6.31. The Committee noted that distribution of the paediatric presentation in particular has been higher than usual to date in 2023, with a noticeable increase in distribution seen in May 2023. The Committee was not aware of any specific reason for the increase seen in May.

*Varicella vaccine*

6.32. The Committee noted that varicella vaccine distribution was reduced during the 2020 COVID-19 lockdown period and had been lower than usual up to June 2021. The Committee noted that distribution returned to normal levels and started tracking higher than usual from late 2022 into 2023.

6.33. The Committee noted that as a result of the 2022 Vaccines RFP, there will be a brand change from Merck Sharp and Dohme's Varivax to GlaxoSmithKline's Varilrix from 1 July 2024.

6.34. The Committee considered that it would like to review varicella epidemiology and evidence for a second varicella vaccine dose in the childhood immunisation schedule at a future meeting.

*Rotavirus oral vaccine*

6.35. The Committee noted that distribution of rotavirus oral vaccine remained steady from year to year. In March 2023, there was a change from oral drops to a squeezable tube presentation.

6.36. The Committee considered that although rotavirus vaccine is included in the childhood immunisation schedule, there has been an increase in outbreaks notified from rest homes and in people presenting to emergency departments in 2023. The Committee considered this could be associated to lower coverage level of vaccination in children.

*Zoster Vaccine (Shingrix)*

6.37. The Committee noted the distribution and expenditure patterns for zoster vaccine.

6.38. The Committee noted that the live attenuated vaccine (Zostavax) was funded until its discontinuation November 2022. The recombinant zoster vaccine (Shingrix) was funded from 1 December 2022. Shingrix has a two-dose schedule, and this is reflected in the steadily increasing distribution seen in 2023.

*Influenza vaccine*

6.39. The Committee noted that immunisation claims for funded influenza vaccine reached a record high of 900,000 doses in 2020 In 2022 and 2023 doses claimed numbered over 800,000.

6.40. The Committee noted that in 2022 and 2023, eligibility was temporarily widened to include Māori and Pacific peoples from 55 to 64 years of age and children under 12

years of age. The Committee noted that funding applications for permanent widened access for these groups have been assessed and ranked on Pharmac's Options for Investment List.

6.41. The Committee noted that funded influenza coverage rates for people over 65 years were: 66% for those of European or Other ethnicity, 57% for Māori and 56% for Pacific peoples and 57% for individuals of Asian ethnicity.

6.42. The Committee noted that as result of the 2022 Vaccines RFP, Viatris will have Principal Supply Status for Influvac Tetra from 1 February 2024. Influvac Tetra is approved for use from 6 months of age, so only one vaccine will be required for all eligible people. This is in contrast to previous years, where more than one vaccine has been required to cover the whole eligible population.

6.43. The Committee noted that a number of combination vaccines combining influenza with COVID-19 and/or Respiratory Syncytial Virus vaccine are currently in development. The Committee considered it would like to consider funding application for combination influenza vaccines at a future meeting.

*COVID-19 vaccine*

6.44. The Committee noted that the COVID-19 vaccine funding is now managed as part of the Combined Pharmaceutical Budget (CPB), and decision-making about funding became Pharmac's responsibility from 1 July 2023.

6.45. The Committee noted that currently the only two funded COVID-19 vaccines available in New Zealand are Pfizer's Comirnaty vaccine and Novavax's Nuvaxovid vaccine.

6.46. The Committee noted that COVID-19 vaccine administration to August 2023 had been lower than the same period in 2022 and 2021.

6.47. The Committee noted that COVID-19 vaccines can be administered at the same time as flu vaccines.

## Review of outstanding funding applications

6.48. The Committee noted that following applications have been ranked on the Options for investment list: Influenza vaccine in Māori and Pacific peoples 50 to 64 years, influenza vaccine widened access options, recombinant zoster vaccine for prevention of herpes zoster and post-herpetic neuralgia in people at 50 years of age and a catch-up program for people 51 to 64 years, people over 65 years of age who require a Shingrix catch-up at least 5 years post Zostavax, meningococcal ACWY conjugate vaccine for children 1 - 4 years of age, children and adolescents 5 - 21 years of age, PCV13 vaccine catch up programme for children 1 - 4 years of age.

6.49. The Committee noted that the following application has been ranked on the cost neutral list: Adjuvanted quadrivalent influenza vaccine for people 65 years of age and over.

6.50. The Committee noted that the following applications would be considered at this meeting: Prevention of herpes zoster in immunocompromised adults; and Prevention of shingles in people with rheumatological conditions treated with a JAK inhibitor or rituximab.

## Update on funding decisions made since last meeting

6.51. The Committee noted that since the last therapeutic group review was considered in August 2021, 7 vaccines funding decisions have been made.

| Vaccine | Indication | Listing Date |
|---|---|---|
| Influenza vaccine | Widened access for Māori and Pacific peoples 55-64 years of age for the 2022 calendar year. | Funded April 2022 |
| Influenza vaccine | Widened access for people with serious mental health conditions or addiction.<br>Widened access for children 3-12 years of age for the 2022 calendar year. | Funded July 2022 |
| PCV13 vaccine | Widened access to PCV13 vaccine for all children in the childhood immunisation schedule. | Funded December 2022 |
| MenACWY vaccine | Funding the MenQuadfi brand of MenACWY vaccine to replace Menactra which was discontinued. | Funded December 2022 |
| MenB vaccine | Widened access to MenB vaccine for children up to 12 months of age with a catch-up for children 13-59 months of age, and people 13-25 years of age who are entering into or in their first year of specified close-living situations. | Funded March 2023 |
| Zoster vaccine | The recombinant zoster vaccine (Shingrix) was funded for people 65 years of age to replace Zostavax, which was discontinued by the supplier. | Funded March 2023 |
| Influenza vaccine | Widened access for Māori and Pacific peoples 55-64 years of age and children 6 months to 12 years of age, for the 2023 calendar year. | Funded April 2023 |

### Update on previous action points

6.52. The Committee noted action points made at previous meetings and the current status of these action points.

6.53. The Committee noted that although a number of these action points were in progress or completed, there were still a number that were yet to be progressed and these would be prioritised by Pharmac staff relative to other Pharmac priorities.

### NPPA applications

6.54. The Committee noted that since September 2019, Pharmac had received a small number of NPPA applications relating to immunisation. These had been for Varicella Zoster vaccine, Meningococcal ACWY vaccine and Human Papillomavirus Vaccine.

## Looking forward

6.55. The Committee noted that Pharmac was aware of a number of new vaccines and, where applicable, was working with the relevant suppliers to seek funding applications for these products in time for the next vaccine commercial process.

6.56. The Committee noted that a number of respiratory syncytial virus (RSV) vaccines are in development, but none are available in New Zealand at this time. The Committee noted that one RSV vaccine (Arexvy) is under evaluation by Medsafe.

6.57. The Committee noted that a 20 valent pneumococcal conjugate vaccine (PCV20) has been approved overseas, but there have, to date, been no applications submitted to Medsafe or Pharmac for this.

6.58. The Committee noted again that there are several combination influenza and COVID-19, or influenza and RSV, vaccines in development and reiterated it would like to review combination influenza vaccines at future meeting.

6.59. The Committee noted a meningococcal ABCWY vaccine was currently undergoing a Phase 3 clinical trial. The Committee also noted a meningococcal ACWXY vaccine was available overseas and considered that this could be considered for use in New Zealand, even though meningococcal serogroup X does not usually circulate in New Zealand.

6.60. The Committee noted that there are a number of vaccines with alternative delivery mechanisms available or in development eg intranasal, intramuscular or dermal patches. The Committee signalled it would be interested in reviewing applications for vaccines with alternative delivery mechanisms.

# 7. Recombinant varicella zoster virus vaccine – Prevention of herpes zoster in immunocompromised adults

## Application

7.1. The Advisory Committee reviewed the application for recombinant varicella zoster virus (RVZV) vaccine in the prevention of herpes zoster (HZ, shingles) in immunocompromised adults.

7.2. The Advisory Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

## Recommendation

7.3. The Advisory Committee made two separate recommendations (7.4 and 7.7) for two age-related groups of people regarding the listing of the RVZV vaccine and a recommendation for the clinical inputs into cost-effectiveness modelling.

7.4. The Advisory Committee **recommended** that the RVZV vaccine eligibility criteria be widened with **high priority** to include people aged 18 years and older who are immunocompromised, within the context of vaccines and immunisations subject to the following Special Authority criteria (new criteria in **bold**):

**Recombinant varicella zoster vaccine [Shingles vaccine]**
**Either:**

1. Two doses for all people aged 65 years; **or**
2. **Two doses for people 18 years of age and over with any of the following:**
    a. **pre- or post-haematopoietic stem cell transplant; or**
    b. **solid organ transplant; or**
    c. **haematological malignancies; or**
    d. **people living with poorly controlled HIV infection; or**
    e. **planned or receiving disease modifying anti-rheumatic drugs (DMARDs) for systemic lupus erythematosus, polymyalgia rheumatica or rheumatoid arthritis; or**
    f. **end stage kidney disease (CKD 4 or 5); or**

**g. primary immunodeficiency.**

7.5. The Advisory Committee **recommended** that the cost-effectiveness modelling of the RVZV vaccine be stratified by people who are immunocompromised at high and/or moderate risk of shingles as defined by the Australian Technical Advisory Group on Immunisation (ATAGI) in the PBAC March 2023 meeting.

7.6. The Committee made these recommendations based on:

7.6.1. The high health need of individuals who are immunocompromised

7.6.2. The evidence that there would be significant health benefit experienced by people who are immunocompromised

7.6.3. The potential cost-savings to the healthcare system

7.6.4. The suitability of vaccine to be given to people who are immunocompromised

7.6.5. The prevention of shingles being more effective in preventing the complications of shingles than the current treatments available.

7.7. The Committee **recommended** that the RVZV vaccine eligibility criteria be widened with **high priority** to include people aged more than 65 years, within the context of vaccines and immunisations subject to the following Special Authority criterion, and in addition to the above recommendation for people who are immunocompromised and aged either 18 to 64 years or over 65 years (new criteria in **bold**):

**Recombinant varicella zoster vaccine [Shingles vaccine]**
Two doses for all people aged 65 years **and older.**

7.8. The Advisory Committee recommended that the cost-effectiveness modelling of the RVZV vaccine be stratified by 65 years and older and by 80 years and older.

7.9. The Committee made these recommendations based on:

7.9.1. The high health need of people who are older than exactly 65 years

7.9.2. People who are immunocompromised experiencing significant health benefits include those affected by the immunosenescence of ageing (ie. the impairment of immune function that occurs naturally with age)

7.9.3. The potential cost-savings to the healthcare system

7.9.4. The suitability of vaccine to be given to people who are older

7.9.5. The prevention of shingles being more effective in preventing the complications of shingles than the current treatments available.

7.10. The Committee considered that while RVZV vaccine has Medsafe approval for people 18 years of age and over who are immunocompromised, people aged 0-17 years who are immunocompromised might benefit from this vaccine, and requested it be able to consider this population at a future meeting when clinical evidence is made available.

## Discussion

*Māori impact*

7.11. The Committee discussed the impact of funding RVZV vaccine for the prevention of shingles on Māori health outcomes. The Committee considered the impact that shingles may have on the individual affected and their whānau may be disproportionally greater compared to non-Māori, non-Pacific peoples due to the well documented barriers experienced by Māori within the healthcare system. The

Committee considered there to be great need to ensure equitable access to this vaccine if it was to be funded.

*Impact on other groups experiencing health inequities*

7.12. The Committee discussed the impact of funding RVZV vaccine on Pacific, disabled, and underserved populations. The Committee noted that although the incidence of shingles does not appear to disproportionately affect Pacific peoples, the impact that shingles may have on the individual affected and their family/whānau may be disproportionally greater compared to non-Māori, non-Pacific peoples due to the barriers experienced by Pacific peoples within the healthcare system. The Committee noted that cost and access to healthcare would affect people more who are experiencing health inequities relative to the wider New Zealand population. The Committee considered there to be great need to ensure equitable access to this vaccine if it was to be funded.

*Background*

7.13. The Committee noted two doses of RVZV are currently funded for people aged 65 years of age.

7.14. The Committee noted it had previously considered at its May 2022 meeting that people aged 18 years or over who are immunocompromised and awaiting solid organ and stem cell transplant, and who have had previous exposure to the varicella virus is a population group that might benefit from this vaccine, and had asked to consider this group further at a future meeting.

*Health need*

7.15. The Committee noted herpes zoster (HZ, shingles) is caused by the varicella zoster virus, which also causes chickenpox. The Committee noted that following chickenpox infection, the virus lies dormant in the nerves near the spine and may re-emerge later as shingles. Varicella zoster virus is usually acquired in childhood, but it is often many decades before the virus reactivates, at times when cellular immunity is compromised and is unable to maintain suppression of the virus. Shingles most commonly affects adults, or people of any age with a weakened immune system.

7.16. The Committee noted shingles is characterised by a painful, unilateral (one side of the body) rash, usually in one area of the body, especially involving the back abdomen or face. The first sign of shingles is often a burning, sharp pain or tingling or numbness under the skin in the area involved, and this can lead to severe itching or aching. Tiredness, fever, chills, headache, and an upset stomach may also occur. Approximately 1 to 14 days after the onset of pain, a rash of small blisters appears on the reddened area of skin.

7.17. The Committee noted the burning pain and blisters follow the distribution of the nerve pathway the reactivated virus has spread from, often extending front to back on one side of the body or head. As with chickenpox infection, after a few days the lesions will crust over. Over the course of several days to weeks, the crusts will drop off and the skin will heal.

7.18. A common complication of shingles is post-herpetic neuralgia (PHN), a chronic, often debilitating pain condition that can last several months or even years. Other sequelae can include ocular complications (herpes zoster ophthalmicus, acute retinal necrosis, Ramsay Hunt syndrome), neurologic complications (encephalitis, aseptic meningitis, peripheral motor neuropathy, myelitis, Guillain-Barré syndrome, stroke syndromes), and secondary bacterial infections of the skin. The incidence of PHN following shingles is high in the elderly and/or in people who are immunocompromised (UpToDate, 2022).

7.19. The Committee noted people can be immunocompromised because of either a medical condition and/or due to medicines and treatments they receive. These include (but are not limited to):

- Congential and acquired immunodeficiencies (T-cell, B-cell and mixed)
- People who have received a haematopoietic stem cell transplant or CART therapy.
- Solid organ transplant
- Haematologic or solid tumour malignancies
- People living with human immunodeficiency virus (HIV) infection
- People with autoimmune conditions and their treatments
- People with chronic kidney disease
- People receiving medicines that affect the immune system such as high-dose corticosteroids (for 2 or more weeks), chemotherapies, immunosuppressants, immune modulators, disease-modifying antirheumatic drugs
- Immunosenescence of ageing.

7.20. The Committee noted for the year 2022/23 approximately 120,000 people received publicly funded immunosuppressants, oncology agents, antiretrovirals, immune modulators and antirheumatic agents in New Zealand. The Committee considered the number of people who are immunosuppressed in New Zealand to be greater than this.

7.21. The Committee noted an analysis of New Zealand general practice electronic records of 391,000 adults and children reported the incidence rate of shingles to be 48.6 cases per 10,000 person-years (95% CI 47.56 -49.6). The age-adjusted incidence for shingles was 29.1 per 10,000 patient-years (95% CI 25.6 -33.1) among Pacific peoples and 38.9 per 10,000 patient-years (95%CI 36.3 -41.6) among Māori (Turner et al. BMJ Open. 2018;8:e021241). The Committee noted that the incidence rates are limited by the unknown numbers of people who are impeded by barriers such as cost, travel, and time to see a general practitioner when experiencing the symptoms and signs of shingles.

7.22. The Committee noted an analysis of 549,870 New Zealand health records, including 38,105 people who were immunosuppressed who were aged ≥45 years (mean age of 71.1±5.0) and unvaccinated for shingles found the incidence rate for shingles in the community was 5.65 per 1000 person-years (95% CI 5.26-6.07) among people who were immunocompromised and 2.66 per 1000 person-year (95% CI 2.59-2.74) among people who were not immunocompromised. The incidence rate of hospitalisation due to shingles was 1.11 per 1000 person-years (95% CI 0.94-1.30) among people who were immunocompromised and 0.25 per 1000 person-years (0.22-0.27) among people who were not immunocompromised. The incidence rate for hospitalisation due to PHN was 0.340 per 1000 person-years (95% CI 0.232-0.429) among people who were immunosuppressed and 0.062 per 1000 person-years (95% CI 0.051-0.074) among people who were not immunosuppressed (Mbinta et al. Lancet Reg Health West Pac. 2022;31:100601).

7.23. The Committee noted that Manatū Hauora reported there were 482 hospitalisations associated with shingles during 2018/2019, with 60% of these hospitalisations occurring among people aged 60 years and older. The Committee considered the burden of shingles to increase substantially after the age of 50 years and then again after the age of 80 due to immunosenescence ie. the impact of ageing on immunity.

7.24. The Committee noted an analysis of 145,397 zoster cases matched to United Kingdom primary care health records reported that the greatest risk factor for shingles is being severely immunocompromised and that recipients of a haematopoietic stem cell transplant were the most at risk (Forbes et al. BMJ. 2014;348:g2911).

7.25. The Committee noted an analysis of German health records involving 9,554,821 (in 2008) and 10,193,093 (in 2012) people aged ≥18 years (median age 49 years) reported that the incidence rate for shingles was 11.5 per 1000 person-years (95% confidence interval (CI) 11.4-11.6) among people who were immunocompromised, 13.4 per 1000 person-years (95% CI 13.2-13.6) among people who were severely immunocompromised, and 5.9 per 1000 person-years among people who were not immunocompromised (Schröder et al. J Infect. 2017;75:207-15). The Committee noted 33.8% of people who were immunocompromised experienced post herpetic neuralgia due to shingles and 22.5% of people who were not immunocompromised (Schröder et al. 2017).

7.26. The Committee noted an analysis of the German rheumatoid arthritis biologic therapy registry (2007-2020), which involved observations of 13,991 people (62,958 people-years) receiving a disease-modifying antirheumatic drugs, reported a total of 559 herpes zoster cases in 533 people with 8.9 events per 1000 person-years (95% CI 8.2-9.6) (Redeker et al. Ann Rheum Dis. 2022;81:41-7). The Committee noted that when adjusted for age, sex, glucocorticoid usage, and indication, the relative risk of herpes zoster was significantly greater for people when receiving a monoclonal anti-TNF antibody (adjusted HR 1.63 [95% CI 1.17- 2.28], p=0.0042), B cell targeted therapy (1.57 [1.03- 2.40] p=0.0355) and JAK inhibitors (3.66 [2.38- 5.63], p<0.0001) when compared to conventional synthetic disease-modifying drugs (Redeker et al. 2022).

7.27. The Committee noted the live zoster vaccine is contraindicated in individuals who are immunocompromised, specifically people with immunodeficiency due to haematological malignancies, acquired immunodeficiency syndrome (AIDS) or clinical manifestations of human immunodeficiency virus (HIV) infection, and in people receiving immunosuppressive medical therapy.

7.28. The Committee noted the following treatment options are available for people who have developed shingles:

7.28.1. For people who are severely immunocompromised or at high risk for serious complications from herpes zoster, intravenous aciclovir is recommended at a dosage of 10 mg/kg IV every 8 hours for 7 to 10 days for adults and 20 mg/kg IV every 8 hours for 7 days for children < 12 years. Some experts recommend treatment beyond 7 to 10 days for the immunocompromised, lasting until all lesions are crusted (Herpes Zoster. MSD Manual, 2022). Alternatively, following initial clinical improvement people can be switched to oral anti-viral and treated until all lesions have crusted over (10-14 days) (Treatment of herpes zoster. UpToDate, 2023).

7.28.2. For people who are less severely immunocompromised, oral valaciclovir is recommended at a dosage of 1g 3 times a day for 7 days, or aciclovir at a dosage of 800mg 5 times a days for 7-14 days (MSDI, 2022).

7.28.3. Management of acute and postherpetic neuralgia can be particularly difficult, for pain relief paracetamol, NSAIDs, opioids, tricyclic antidepressants or gabapentin can be used (MSD, 2022; BPAC. The diagnosis and management of herpes zoster and its complications. 2014).

7.29. The Committee noted varicella zoster virus is contagious, and individuals hospitalised with shingles who are immunocompromised need to be cared for in a single negative-pressure isolation room, with healthcare workers employing airborne and contact infection prevention and control measures until disseminated disease is ruled out. Affected immunocompetent individuals only require standard precautions to be undertaken.

7.30. The Committee noted some people with shingles do not recover enough to return to independent living, which can impact carers of the affected individuals, including partners, relatives, whānau and friends (Scott et al. Vaccine. 2006;24:1308-14). The Committee noted the high cost associated with residential care for older people. The Committee noted that some people may also not be able to continue to undertake employment, which may further impact family or dependents.

7.31. The Committee noted the incidence of shingles does not appear to disproportionately affect Māori, however the impact that shingles may have on the individual affected and their whānau may be disproportionally greater compared to non-Māori, non-Pacific peoples due to the barriers experienced by Māori within the healthcare system. The Committee considered there to be great need to ensure equitable access to this vaccine if it was to be funded.

7.32. The Committee noted the incidence of shingles does not disproportionately affect Pacific peoples however the impact that shingles may have on the individual affected and their family or whānau may be disproportionally greater compared to non-Māori, non-Pacific peoples due to the barriers experienced by Pacific peoples within the healthcare system. The Committee considered there to be great need to ensure equitable access to this vaccine if it was to be funded.

7.33. The Committee noted that people with end-stage kidney disease (ESKD) and on renal replacement therapies are immunocompromised. Māori and Pacific peoples experience disproportionally greater rates of ESKD compared to non-Māori and non-Pacific peoples and therefore would experience health benefit if the vaccination was to be available.

7.34. The Committee noted that cost and access to healthcare would affect people experiencing health inequities relative to the wider New Zealand population.

7.35. The Committee reprised that at its May 2022 meeting, it had recommended funding for people of Māori or Pacific ethnicity aged 60 years or older. The Committee noted that Māori and Pacific peoples overall experience a shorter life expectancy than non-Māori, non-Pacific peoples and reiterated that it considered that the age of access should be lowered relative to this.

7.36. The Committee considered there to be strong evidence that immunocompromised people (due to conditions, medicines, or age) are at greater risk of developing and/or having more frequent episodes of shingles and experiencing severe complications as a consequence. The Committee considered prevention of shingles would preserve a person's quality of life, alongside that of their family or whānau and mitigate the potential cost to the healthcare system including hospitalisations and oral prophylaxis.

*Health benefit*

7.37. The Committee noted varicella zoster vaccine is a recombinant subunit vaccine, containing the recombinant VZV envelope glycoprotein E antigen, that is reconstituted at the time of use with the adjuvant $AS01_B$. The adjuvant induces activation of the innate immune system, ultimately resulting in generation of glycoprotein E-specific CD4+ T cells and antibodies.

7.38. The Committee noted varicella zoster vaccine is indicated by Medsafe for the prevention of herpes zoster and post-herpetic neuralgia (PHN) in people 50 years of age or older; and adults 18 years of age or older at increased risk of herpes zoster.

7.39. The Committee noted the varicella zoster vaccine is administered in two doses of 0.5mL each, an initial dose followed by a second dose 2-6 months later. Medsafe reports that people who are immunocompromised, or likely to become immunocompromised, can receive the second dose 1-2 months following initial dose.

7.40. The Committee noted the following clinical evidence relating to the efficacy and safety of RVZV vaccine:

7.40.1. Bastida et al. JAMA.2019;322:123-33

7.40.2. Dagnew et al. Lancet Infect Dis. 2019;19:988-1000

7.40.3. Vink et al. Clin Infect Dis. 2020; 70:181-190

7.40.4. Venerito et al. Int J Mol Sci. 2023;24:6967

7.41. The Committee considered RVZV vaccine to be an effective vaccination and can be given to people who are immunocompromised, unlike the live-attenuated zoster vaccine.

7.42. The Committee noted that preventing shingles and its complications would likely have health benefits for carers, family and whānau.

7.43. The Committee noted the duration of effectiveness of RVZV vaccine to prevent shingles is unknown and considered it difficult to determine whether people would need another vaccination. The Committee noted follow-up studies for the ZOE-50 and ZOE-70 clinical trials report an annual vaccine efficacy estimate of >84% for each year since vaccination, suggesting that the clinical benefit of RVZV vaccine in people aged ≥ 50 years and older is sustained for at least 7 years post-vaccination (Boutry et al. Clin Infect Dis. 2022;74:1459-67). The Committee noted these studies did not include people who are immunocompromised.

*Cost and savings*

7.44. The Committee considered that funding the RVZV vaccine would result in significantly fewer primary care consultations as fewer people would be expected to develop shingles and PHN.

7.45. The Committee considered that if funded, the likely uptake of the RVZV vaccine in people who are immunocompromised would be in the range of 50-80%, but noted that 100% of severely immunocompromised (ie those who had received stem cell transplants) people would receive it.

7.46. The Committee considered the uptake to be similar to the uptake of the influenza vaccine among people who are 65 years and among Māori and Pacific peoples who are 55 years and older.

7.47. The Committee noted treatments for shingles and PHN such as valaciclovir would still be given to the immunocompromised population in the case of vaccine failure.

7.48. The Committee noted RVZV vaccine can be co-administered with the influenza vaccination, this would require a person to receive two vaccinations in one appointment and the savings are likely to be minimal.

7.49. The Committee noted that vaccine efficacy was likely to wane more quickly in people who are severely immunocompromised than in the 65 years of age and over population.

7.50. The Committee noted that it would be appropriate to adapt the efficacy waning assumptions used in previous modelling of RVZV vaccine for the subgroups defined by age. The Committee noted the lack of evidence reporting on the efficacy waning for the people who are immunocompromised and with the absence of data, considered it appropriate to adjust previous modelling based on the ZOE-50 and ZOE-70 clinical trials. The Committee expressed interest in discussing the appropriate time for revaccination when data are published.

*Funding criteria*

7.51. The Committee noted the risk of shingles can vary depending on the level of immunocompromise. The Committee noted the March 2023 meeting record of the Pharmaceutical Benefits Advisory Committee (PBAC) that cited Australian Technical Advisory Group on Immunisation (ATAGI) advice identifying the medical sub-groups who are of high, moderate, and low risk of shingles, presented in the table below:

| | |
|---|---|
| High risk | • stem cell transplant recipients<br>• solid organ transplant recipients<br>• people with haematological malignancies and advanced or untreated HIV with CD4 counts <250/ µL or those with a higher CD4 count unable to be established on effective anti-retroviral therapy<br>• individuals receiving regular high doses of systemic corticosteroids, disease modifying anti-rheumatic drugs, or chemotherapy |
| Moderate risk | • systemic lupus erythematosus<br>• rheumatoid arthritis |
| Low risk | • solid organ malignancies<br>• inflammatory bowel disease<br>• end-stage renal disease<br>• asthma<br>• diabetes<br>• depression<br>• chronic obstructive pulmonary disease |

7.52. The Committee noted that there is a cumulative risk for people with 'low-risk' conditions as they age which means some people would have a greater risk of shingles.

7.53. The Committee noted ATAGI's consideration that people who are immunocompromised with a moderate risk of shingles are at greater risk of shingles and its complications compared to individuals who are aged 65 years and older.

7.54. The Committee noted the Pharmac COVID-19 antiviral treatment access criteria identifying severely immunocompromised people.

7.55. The Committee noted its concern that a Special Authority containing lists of specific conditions and medicines may unintentionally exclude people who have a severe or moderate risk of shingles and would benefit from vaccination.

7.56. The Committee considered the following Special Authority criteria would include people who are immunocompromised and have similar or greater risk of shingles and its complications compared to people not immunocompromised aged 65 years or older.

**Recombinant varicella zoster vaccine [Shingles vaccine]**
Either:
1. Two doses for all people aged 65 years; or
2. Two doses for people with any of the following:
    a. pre- or post-haematopoietic stem cell transplant; or

b. solid organ transplant; or
c. haematological malignancies; or
d. people living with poorly controlled HIV infection; or
e. planned or receiving disease modifying anti-rheumatic drugs (DMARDs) for systemic lupus erythematosus, polymyalgia rheumatica or rheumatoid arthritis; or
f. end stage kidney disease (CKD 4 or 5); or
g. primary immunodeficiency.

7.57. The Committee further considered RVZV vaccine should be funded for people aged more than 65 years, additional to immunocompromised people of that age already within the above Special Authority criteria.

*Summary for assessment*

7.58. The Committee considered that the tables below summarise its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for the RVZV vaccine if it were to be funded in New Zealand for the prevention of herpes zoster when immunocompromised, including by age. These PICOs capture key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. The PICOs are based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICOs may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

*Immunocompromised population*

| | |
|---|---|
| Population | Individuals aged 18-64 years and over 65 years (the varicella zoster vaccine is currently funded for people aged exactly 65 years) who are immunocompromised, as defined by the Special Authority criteria. |
| Intervention | Two 0.5mL doses of recombinant varicella zoster vaccine (SHINGRIX) spaced 1-2 months apart.<br><br>Those who develop shingles currently either receive supportive care, or a valaciclovir antiviral course and additional treatments for PHN, as per previous modelling of the varicella vaccine. |
| Comparator(s) | No vaccination plus antiviral treatment for those with HZ and PHN |
| Outcome(s) | Reduction in HZ and PHN as per trial evidence for each subgroup. For example, the Bastida et al. 2019 trial in those who had received an autologous HSCT reported a 68% reduction in HZ infection and 78% reduction in PHN at a median follow-up of 21 months.<br><br>A reduction in HZ and PHN results in:<br>• Lower HZ-related mortality<br>• Improved health-related quality of life<br>• Reduced inpatient and outpatient events |
| Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the target population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data. | |

*Wider population*

| | |
|---|---|
| Population | Individuals aged 65 years and over |
| Intervention | Two 0.5mL doses of recombinant varicella zoster vaccine (SHINGRIX) spaced 1-2 months apart.<br><br>Those who develop shingles currently either receive supportive care, or a valaciclovir antiviral course and additional treatments for PHN, as per previous modelling of the varicella vaccine. |

| | |
|---|---|
| Comparator(s) | No vaccination plus antiviral treatment for those with HZ and PHN |
| Outcome(s) | Reduction in HZ and PHN as per trial evidence for each subgroup. For example, the Bastida et al. 2019 trial in those who had received an autologous HSCT reported a 68% reduction in HZ infection and 78% reduction in PHN at a median follow-up of 21 months.<br><br>A reduction in HZ and PHN results in:<br>• Lower HZ-related mortality<br>• Improved health-related quality of life<br>Reduced inpatient and outpatient events |
| Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the target population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data. | |

## 8. Meningococcal B vaccine – invasive meningococcal disease – All adolescents 13-25 years

### Application

8.1. The Advisory Committee reviewed the application for meningococcal B vaccine for the prevention of invasive meningococcal disease for all adolescents 13-to-25 years.

8.2. The Advisory Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

### Recommendation

8.3. The Advisory Committee recommended that application be **declined** within the context of vaccines and immunisation.

8.4. In making this recommendation, the Advisory Committee considered:

- those in close living situations and other high-risk groups within the 13-to-25-year age group were most important to target as evidence supports reduction of risk for the individual, but evidence for herd immunity with meningococcal B vaccination is not available
- a universal 4CMenB vaccination programme for people 13-to-25 years was not proportionate to the risk that meningococcal disease poses to the wider community at this time
- that the likely health benefit associated with a universal meningococcal B vaccination programme for people 13 to 25 years would be limited, due to the short duration of protection and lack of evidence that high coverage would be associated with herd immunity
- the high and uncertain level of upfront and ongoing costs to deliver primary course and booster doses of meningococcal B multicomponent vaccine (4CMenB) to a large group of people
- the savings to the health sector that may result from the prevention of invasive meningococcal disease and long-term complications of disease.

### Discussion

*Māori impact*

8.5. The Committee discussed the impact of funding 4CMenB for the prevention of meningococcal disease on Māori health areas of focus and Māori health outcomes. The Committee noted that its previous advice in May 2018 that meningococcal disease disproportionately affects Māori. The Committee considered that wāhine

Māori are also disproportionately impacted by gonorrhoeal infections. The Committee noted that non-respiratory communicable disease (which would include meningococcal disease and sexually-transmitted infections) is not considered to be a part of Pharmac's Hauora Arotahi (Māori health areas health areas of focus as voiced to Pharmac by whānau Māori in 2018).

8.6. Noting the low proportion of rangatahi involved in the previous consultation process and development of the Hauora Arotahi, the Committee recommended there be increased engagement with this population group in the future when exploring health needs.

*Impact on Pacific peoples, disabled people, tāngata whaikaha Māori, and other people who have been underserved by the health system*

8.7. The Committee discussed the impact of funding of universal 4CMenB vaccination in people 13-25 years on Pacific, disabled, and underserved populations. The Committee noted that its previous advice in May 2018 that meningococcal disease disproportionately affects infants (ie children under 1 year of age) and Pacific peoples. The Committee noted its previous advice in May 2018 that Pacific peoples have a four times higher incidence across all age groups. Members noted the high incidence of long-term morbidity and disability from invasive meningococcal disease sequelae in disease survivors.

*Background*

8.8. The Committee noted that the 4CMenB vaccine is currently funded for children up to 12 months of age with a catch-up for children 12 to 59 months of age until 2025. The Committee noted that 4CMenB vaccine is funded for people aged 13 to 25 years (inclusive) who are either entering (within the next three months), or in their first year of, living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences or prisons. The Committee noted that there was a catch-up programme for people 13 to 25 years (inclusive) who are already living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons until February 2024.

8.9. The Committee noted that when it last reviewed 4CMenB, in May 2018, evidence for both meningococcal disease and gonorrhoea was considered.

*Health need*

8.10. The Committee noted that invasive meningococcal disease (IMD) is a rapidly progressing disease that is easily mis-diagnosed, with a 10% associated mortality rate and 20% of survivors experiencing major permanent disability as a result. The Committee noted an observational study using data from 1996-2006 during the meningococcal B outbreak in New Zealand reporting that of the 318 children with IMD in the time period, 4.1% died and 23.8% experienced resulting impairment from their acute infection (Burton et al. Emerg Infect Dis. 2023;29:686-95).

8.11. The Committee noted evidence that the long-term impact of IMD on individuals, family and whānau is often underreported in observational studies and therefore could be underestimated in economic evaluations (Shen et al. BMC Public Health. 2022;22:1078).

8.12. The Committee noted case study information provided by the applicant about the experience of an individual and their family with IMD. The Committee noted that the individual required a helicopter transfer, time in ICU, numerous blood tests, blood gas tests, X-rays, MRIs, and CT scans, as well as surgery and a range of other procedures. The Committee considered the profound impact that IMD had on the person and their family/whānau and the health system.

8.13. The Committee noted that from 1 January 2023 up to 18 August 2023 there were 11 cases of meningococcal B disease notified, with three notified deaths. The Committee noted that 10 out of 11 cases were notified in the North Island of New Zealand.

8.14. The Committee noted in 2022 there were 72 cases of meningococcal disease notified and three deaths notified, including one person aged 13 to 19 years. The Committee noted that the six cases in the 15–19-year age group in 2022 were of Māori, Middle Eastern, Latin American or African ethnicity (MELAA) or NZ European ethnicity.

8.15. The Committee considered that the decrease in cases since 2020 was related to the COVID-19 pandemic and public health population infection control measures undertaken over this time. The Committee considered that the epidemiological data would change over time as the public health measures are lifted.

8.16. The Committee noted its previous advice in May 2018 that meningococcal disease disproportionately affects infants under 1 year of age, and Māori and Pacific peoples (rates of 2.6 per 100,000 population and 4.2 per 100,000 population, respectively over the period 2007-2016) and that this inequity was less pronounced in more recent years (up to 2018).

8.17. The Committee noted its previous advice in May 2018 that Pacific peoples have a four times higher case incidence across all age groups.

8.18. The Committee considered that people living rurally face often face more barriers to accessing health care than people living in urban centres. The Committee considered that this impact on access can have a significant influence on the immunisation status of populations experiencing health inequity (Nowlan et al. NZ Med J. 2019;139:79-88).

8.19. The Committee noted that disabled people are four times more likely to report poorer health status (New Zealand Health Survey 2021/22) and report social and financial disadvantages that are known to impact housing and health (Report on economic inclusion and social mobility. Productivity Commission – Te Kōmihana Whai Hua o Aotearoa. 2023).

8.20. The Committee noted that in 2022 there were 6969 notified cases of people with gonorrhoea. The Committee noted that gonorrhoea predominately affects people aged 20-39 years and considered that this was a similar age group to those affected by meningococcal disease. The Committee noted that there were inequities in cases who identify as men who have sex with men (MSM) (5816 cases per 100,000 population) compared to men who have sex with women (MSW) (105 cases per 100,000 population). The Committee noted that for women who have sex with men (WSM), Māori were inequitably burdened, compromising 52% of all WSM who were notified as cases (ESR Sexually Transmitted Infections in New Zealand: Supplementary Annual Surveillance Report 2022).

*Health benefit*

8.21. The Committee noted that South Australia has a universal 4CMenB vaccination programme for school students from Year 10 (aged 14-15 years) to aged 20 years. The Committee noted that in Canada people aged 12 to 24 years are eligible for 4CMenB depending on individual preferences and regional epidemiology and strain susceptibility (Meningococcal vaccine: Canadian Immunization Guide). The Committee noted that the ACIP in the United States recommends 4CMenB vaccination of young people 16 to 23 years based on shared patient-practitioner decision making (Mbaeyi et al. 2020;69:1-41).

8.22. The Committee noted a phase III, randomised, double-blind, control trial in university students aged 18-24 years from ten sites in England randomly assigned (1:1:1) to receive two doses 1 month apart of Japanese encephalitis vaccine or 4CmenB

vaccine or one dose of Meningococcal ACWY vaccine (MenACWY) then one dose of placebo. The Committee noted that 4CmenB did not result in statistically significant reduction in nasal carriage of any *Neisseria meningitidis* bacterial strain compared to control. The Committee noted that secondary analyses identified a significant reduction in the overall *N. meningitidis* carriage in 4CmenB-vaccinated compared to unvaccinated adolescents (Read et al. Lancet. 2014;384(9960):2123-31). The Committee considered that the secondary analysis results support the conclusion that both MenACWY and 4CmenB have an effect on *N. meningitidis* carriage. The Committee considered that this was not a study evaluating herd immunity and therefore a reduction in carriage did not translate to herd immunity.

8.23. The Committee noted a cluster randomised trial in South Australia school students in Years 10 to 12 involving 24,269 participants over 12 months. The Committee noted that there was no reported statistical difference in *N. meningitidis* carriage between vaccinated and unvaccinated groups (adjusted odds ratio, 1.02; 95% CI, 0.80 to 1.31; *P*=0.85) (Marshall et al. N Engl J Med. 2020;382:318-27). The Committee considered that this was high strength evidence. The Committee considered that the population effect was low due to the low number of cases compared to the total population.

8.24. The Committee noted a repeat cross-sectional study to assess carriage prevalence in school leavers (first year after final year of senior school) in 2018 and 2019 after offering 4CmenB vaccination to senior school students in South Australia in 2017 and 2018 involving 4104 participants (McMillian et al. J Infect Dis. 2022;225:637-49). The Committee noted that any reported meningococcal carriage was significantly lower in vaccinated participants compared to unvaccinated participants (adjusted odds ratio: 0.83; 95% CI, 0.70–0.98; *P*= 0.03).

8.25. The Committee noted a retrospective case-control study of people attending sexual health clinics aged 13 to 25 years who had been vaccinated with New Zealand meningococcal B vaccine (MeNZB) and diagnosed with gonorrhoea or chlamydia, or both. The Committee noted that it was reported that vaccinated individuals were significantly less likely to be cases than controls (adjusted odds ratio 0.69, 95% CI 0.61-0.79; *P*<0.0001) (Petousis-Harris et al. Lancet. 2017;390:1603-10).

8.26. The Committee noted a retrospective cohort study aimed to estimate the effectiveness of the MeNZB against gonorrhoea-associated hospitalisation involving 935,496 people (Paynter et al. Vaccines (Basel). 2019;7:5). The Committee noted the reported reduction in hospitalisation for gonorrhoea was estimated to be 24% (95% CI 1–42%) after adjustment for gender, ethnicity, and deprivation.

8.27. The Committee noted a retrospective cohort study in people aged 16-23 years in two US cities involving 165 000 STI infections reported among 109,000 individuals that evaluated the effectiveness of a 4CmenB vaccine. The Committee noted that complete MenB-4C vaccination series was 40% (95% CI 23–53) effective against gonorrhoea and partial MenB-4C vaccination series was 26% (95% CI, 12–37) effective (Abara et al. Lancet Infect Dis. 2022;22:1021-9). The Committee noted that the reported vaccine effectiveness against gonorrhoea observed in this study is comparable with the 31% effectiveness of MeNZB against gonorrhoea reported in the New Zealand studies.

8.28. The Committee noted the additional following evidence:

- Ladhani et al. Clin Infect Dis. 2021;73:e1661-8
- McMillian et al. Expert Rev Vaccines. 2022;103-4
- Martinon-Torres et al. J Infect. 2021;83:17-26

8.29. The Committee considered that, while not the primary intent of meningococcal vaccination programmes, there was sufficient evidence to include protection against

infection caused by *Neisseria gonorrhoeae* in future economic assessments of 4CmenB and other serogroup B-containing vaccines. The Committee considered that protection against gonorrhoea infection, even if modest, would be relatively impactful on a population level for the 13 to 25 years age group given the large numbers of gonococcal infections reported in this age group relative to other age groups.

8.30. The Committee considered that a key uncertainty in the benefit derived from 4CmenB in those 13 to 25 years old was the duration of protection, which refers to the period after vaccination where the individual experiences some, or all, of the potential protective effect of the vaccine. The Committee considered that the duration of protection against invasive meningococcal disease and gonorrhoea infection were likely to be different, although there was but limited evidence to inform the latter.

8.31. The Committee considered that, based on the available evidence, it was reasonable to assume a duration of protection against invasive meningococcal disease caused by Neisseria *meningitidis* serogroup B of at least five years after receipt of the second vaccine dose. The Committee noted that antibody titres after 4CmenB vaccination remain at seroprotective levels for a limited duration before rapidly declining over subsequent months and that antibody titres against some meningococcal serogroup B antigens decline faster than others (Santolaya et al. Hum Vacc Immunother. 2013;9: 2304-10). The Committee noted that immunogenicity bridging data was available to inform the rate of antibody titre decline, but that the effective level of protection afforded by these antibody titres depended on strain coverage of the vaccine.

8.32. The Committee considered that the duration of protection against gonorrhoea was highly uncertain due to limited available evidence. The Committee noted that the protective effect of the MeNZB vaccine appeared to wane in the years after receiving the vaccine but the study results were difficult to interpret due to wide confidence intervals (Petousis-Harris et al. Lancet. 2017;390:1603-10). The Committee considered however that it would be reasonable to assume that the evidence on the effectiveness of MeNZB vaccination programme against gonorrhoea in New Zealand was likely to be representative of the level of protection that 4CmenB vaccination programmes could provide in the 13-to-25-year age group, given both MeNZB and 4CmenB vaccine contain outer membrane vesicle antigens that are shared between *Neisseria meningitidis* and *Neisseria gonorrhoeae*.

*Suitability*

8.33. The Committee considered that the vaccine is currently used in practice and packaged as a one dose vaccine for ease of administration.

*Cost and savings*

8.34. The Committee noted that the proposed age group 13 to 25 years was a wide age band comprising over 600,000 individuals. The Committee considered that the amount of investment required for this proposal would depend on the total number of doses required for individuals during the seven-year period for this age cohort. The Committee considered that this would be based on the recommended age they would receive these doses and whether individuals could be eligible for booster doses after the primary course.

8.35. The Committee considered that, due to the limited duration of protection and lack of evidence of herd immunity, booster doses would need to be administered after a primary course to ensure sufficient protection over the seven-year period an individual would remain in this age cohort. The Committee considered that this would have programmatic implications regarding the age at which individuals would be first offered vaccination and the spacing between doses, as well as the total cost of the vaccination programme.

8.36. The Committee noted that there are very few vaccines funded for individuals aged 13 to 25, which meant the likely uptake of 4CMenB among the age group was uncertain. The Committee considered that observed uptake of meningococcal vaccination during the 2019 outbreak in Northland provided an indication of the level of uptake that could be achieved by a universal vaccination programme. The Committee noted that the 2019 outbreak response included a vaccination programme with widespread vaccine availability across medical centres and schools, and active outreach to rural areas.

8.37. The Committee noted that there was currently no established infrastructure to deliver vaccines in high school settings and there would be set up costs associated with setting up and maintaining a new vaccination programme. The Committee also noted that there may be incremental costs, due to vaccinator fees and other administrative costs.

8.38. The Committee noted that widening access to vaccines could result in health sector budget savings due to reduced disease burden in the population. The Committee considered that the most material savings to the health sector may result from a reduction in the number of hospitalisations for the treatment of invasive meningococcal disease, a reduction in the need for health services for the treatment of sequelae, and a reduction in the risk of outbreaks, which often require a management response by public health services, including the administration of preventive measures to close contacts. The Committee considered that any savings would depend on uptake of the vaccine and the number of cases prevented compared to the current access criteria.

*Summary for assessment*

8.39. The Advisory Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for 4CmenB if it were to be funded in New Zealand for all individuals aged 13 to 25 years. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Advisory Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

| | |
|---|---|
| Population | Individuals aged 13 to 25 years who are not already eligible for meningococcal vaccination under the current access criteria (ie entering or in the first year of being in specified close-living situations, or at high risk of meningococcal disease due to other specified reasons). |
| Intervention | Meningococcal B vaccine, administered as an intramuscular injection, and in a dosing schedule as follows:<br><br>Two doses, not less than one month apart, administered at 16 years of age. |
| Comparator(s) | No vaccination |

| | |
|---|---|
| Outcome(s) | Reduction in risk of developing invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B.<br>• Vaccine effectiveness (VE) of a two-dose schedule assumed to be 82·9% (95% CI 24·1 to 95·2) over the first year after receipt of the second dose (Parikh et al. Lancet. 2016;388:2775-82)<br>• VE assumed to wane over time, with the total duration of protection highly uncertain but assumed to be at least three years.<br>• VE assumed to be similar between infants (as reported in Parikh et al [2016]) and adolescents.<br>• No indirect protection to unvaccinated individuals, because 4CMenB is not associated with a reduction in nasopharyngeal carriage (Marshall et al. N Engl J Med. 2020;382:18-27)<br>Reduction in risk of acquiring infection caused by *Neisseria gonorrhoeae*<br>• Vaccine effectiveness (VE) of a two-dose schedule assumed to be 40% (95% CI 25 to 53%) during the three years following receipt of the second dose (Abara et al. Lancet Infect Dis. 2022;22:1021-9)<br>• VE assumed to wane over time, with the total duration of protection highly uncertain but assumed to be at least three years.<br>. |
| Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the target population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data. | |

## 9. COVID-19 vaccine - background on current access criteria

### Application

9.1. The Advisory Committee reviewed the COVID-19 booster vaccination eligibility criteria for New Zealand as worded on the Manatū Hauora - Ministry of Health website.

9.2. The Advisory Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

### Recommendation

9.3. The Advisory Committee **recommended** that **primary COVID-19 vaccination** continue to be funded for the following people:

1) anyone aged over 5 years
2) children aged 6 months to 4 years with eligible comorbidities.

9.4. The Advisory Committee **recommended** that the groups eligible for funded **COVID-19 booster vaccination** be as follows:

1) Anyone over 65 years old, or
2) Māori and Pacific peoples aged 50 years and over, or
3) Pregnant people, or
4) People with disabilities with significant or complex health needs, including those who receive Ministry of Health Disability Support Services, or
5) People with serious mental health conditions including: schizophrenia, bipolar disorder, major depressive disorder or schizoaffective disorder, addiction, or

6) People with at least Class II obesity, or
7) People aged 12 years or over years with a medical condition that increases the risk of severe illness including:
    i) cardiovascular disease
    ii) chronic respiratory disease
    iii) chronic renal disease
    iv) neuromuscular and CNS diseases/disorders
    v) diabetes
    vi) complex genetic, metabolic disease or multiple congenital anomalies including Trisomy 21 (Down syndrome)
    vii) immunosuppression or immune deficiency
    viii) transplant recipient
    ix) pre and post splenectomy
    x) errors of metabolism at risk of major metabolic decompensation
    xi) cancer.

9.5. The Advisory Committee considered the following in making these recommendations:

- Booster vaccination reduces severe disease and death from COVID-19
- The increased risk of severe COVID-19 outcomes in priority groups and the unequal health need of the currently funded groups
- Waning of antibody and cellular immunity in different groups
- Health system impacts and the confusion over groups funded for booster vaccination.

## Discussion

*Māori impact*

9.6. The Committee discussed the impact of the recommended eligibility criteria on Māori health areas of focus and Māori health outcomes. The Committee considered that Māori have a higher age-standardised risk of hospitalisation associated with COVID-19 overall and mortality and should be prioritised for continued vaccination. The Committee considered that those living rurally likely had a higher risk, but this was not quantifiable. The Committee noted that, in general, rural communities have a higher proportion of Māori, have demographically older age populations, are associated with geographical areas of higher socioeconomic deprivation and have greater difficultly accessing vaccines, all of which increase the risk of severe COVID-19 outcomes. The Committee noted that vaccination is not a part of Pharmac's Hauora Arotahi (Māori health areas of focus).

*Impact on Pacific peoples, disabled people, tāngata whaikaha Māori, and other people who have been underserved by the health system*

9.7. The Committee discussed the impact of the recommended eligibility criteria on Pacific, disabled, and underserved populations.

9.8. The Committee noted that Pacific peoples have a higher age- standardised risk of hospitalisation overall and mortality and considered they should be prioritised for continued vaccination.

9.9. The Committee considered that people receiving Disability Support Services (DSS) funding comprise a vulnerable, high needs group of people with varying intellectual or physical disabilities. The Committee considered that the data for the risks of hospitalisation and mortality from the general population was not generalisable to all

disabled people in New Zealand. The Committee considered that disabled people were an important group to prioritise for continued vaccination.

*Background*

9.10. The Committee noted that a second COVID-19 booster vaccination is currently funded for anyone over 30 years old. The Committee noted that primary COVID-19 vaccination is funded for anyone 5 years and over and children 6 months to 4 years and 11 months with certain comorbidities. The Committee noted that these criteria were decided by Manatū Hauora - Ministry of Health on advice from the Ministry's COVID-19 Vaccination Technical Advisory Group, and that Pharmac will be responsible for the eligibility criteria going forward.

9.11. The Committee noted that at the time of the meeting, Te Whatu Ora - Health New Zealand prioritised the following groups for booster vaccination:

- All people over 65 years old
- Māori and Pacific people aged 50 and over
- Pregnant people with underlying health conditions that put them at higher risk of severe illness from COVID-19
- People with disability with significant or complex health needs
- People with serious mental health conditions
- Young people aged 12 to 15 who have a medical condition that increases the risk of severe illness from COVID-19.

9.12. The Committee noted that at the time of this meeting the currently available COVID-19 vaccines in New Zealand include:

- Comirnaty (concentrate or solution for injection 30 µg/0.3 mL) Original vaccine, provisional consent for individuals 12 years of age and older
- Comirnaty (concentrate for injection 10 µg/0.2 mL) Original vaccine provisionally consented for individuals 5 to 11 years of age.
- Comirnaty (concentrate for injection 3 µg/0.2 mL) Original vaccine provisionally consented for infants and children aged 6 months to 4 years.
- Comirnaty Original/Omicron BA.4/5 (solution for injection 15/15 µg/0.3 mL), provisionally consented as a booster dose for individuals 12 years of age and older after primary vaccination.
- Nuvaxovid Original vaccine, provisionally consented for individuals 12 years of age and older.

9.13. The Committee noted its previous consideration of COVID-19 vaccination when it reviewed the use of different COVID-19 variant strains for vaccination in New Zealand in October 2023.

*Health need*

9.14. The Committee noted daily hospital admissions and deaths for COVID-19 per 100,000 population during 12 months to September 2023 (7-day rolling average) stratified by age and noted that there was a persistent trend that older age is associated with higher hospital admissions (Te Whatu Ora. COVID-19 trends and Insights. Admissions by age and deaths by age). The Committee considered that this trend persisted regardless of surges in case numbers. The Committee noted that the majority of the hospitalisations and deaths occur in the 80 years and over age group.

9.15. The Committee considered hospitalisation data from a multivariate logistic regression using data from Northern regions as presented by Dr Colin McArthur to the COVID-19 Treatments Advisory Group in May 2022. The Committee noted that this evaluated the risk of hospitalisation of different groups within each at risk group including age (5 year groups), vaccination status, and ethnicity (Māori, Pacific peoples, Asian and all other ethnicities combined) and considered that the highest risk of hospitalisation is in older people (adjusted odds ratio (aOR): 40.0 in those 80 years or over compared to those 15-19 years) then the unvaccinated (aOR: 5.62 compared to primary course with booster) followed by Pacific peoples (aOR: 1.52) and then Māori (aOR: 1.30). The Committee considered that people 50 to 74 years likely had a lower risk of hospitalisation overall and that the risk is increased in those over 75 years, with this risk being further increased in people without a primary vaccination course and those of Māori or Pacific ethnicity.

9.16. The Committee noted that the age-standardised risk of mortality attributed to COVID-19 is increased in those living in high deprivation that trends upwards as deprivation increases and those of Māori or Pacific ethnicity compared to those of New Zealand European or Other ethnicity (COVID-19 Mortality in Aotearoa New Zealand. September 2022). The Committee noted a further analysis from 2020 that also reported increased mortality for Māori compared with other ethnic groups (Steyn et al. N Z Med J. 2021;134:28-43).

9.17. The Committee noted data from the Centres for Disease Control (CDC) from >800 hospitals in the United States (US) on age-adjusted relative risks for ICU admission for COVID-19 with increasing 'likely underlying' comorbid conditions (Kompaniyets et al. Prev Chronic Dis. 2021:18:E66), and considered that as the number of underlying comorbid conditions increases the relative risk of ICU admission also increases.

9.18. The Committee noted New Zealand data reported that people with moderate comorbidity had an age, sex, ethnicity, and vaccination-adjusted risk of mortality three times (95% CI, 2.6-3.5) that of those with no comorbidities, and people with severe comorbidity had a corresponding adjusted risk of mortality 14.3 times (95% CI, 12.2-16.7) that of no comorbidities (COVID-19 Mortality in Aotearoa New Zealand. Public Health Agency, September 2022). The Committee noted that comorbidity severity was identified using the M3 Multimorbidity index, an updated, validated mortality index for short-term mortality risk that uses chronic conditions identified from routine National Minimum Dataset ICD-10 hospital admission data, where each individual condition is weighted to reflect its contribution to one-year mortality risk, with weights then summed to produce a patient-level score of comorbidity severity (Stanley & Sarfari. J Clin Epidemiol. 2017:92:99-110).

9.19. The Committee considered people with chronic medical conditions are at higher risk of severe COVID-19. The Committee noted the CDC analysis (Kompaniyets et al. 2021) reported that the strongest risk factors for death in hospitalised adults in the US were obesity (adjusted risk ratio [aRR] = 1.30; 95% CI, 1.27-1.33), anxiety and fear-related disorders (aRR = 1.28; 95% CI, 1.25-1.31), and diabetes with complications (aRR = 1.26; 95% CI, 1.24-1.28), and for total counts of conditions the aRRs of death ranged from 1.53 (95% CI, 1.41-1.67) for people with 1 condition to 3.82 (95% CI, 3.45–4.23) for people with more than 10 conditions (compared with people with no conditions)).

9.20. The Committee noted a French observational study using data from 28 million vaccinated (two doses) individuals up to August 2021 to estimate risk of COVID-19 -related hospitalisation or in-hospital death adjusted for age, gender, deprivation index, comorbidities (Semenzatro et al. Lancet Reg Health Eur. 2022:19:100441). The Committee noted that 47 chronic conditions were associated with COVID-19 hospitalisation and death. The Committee noted that the strongest association was in

people with kidney transplantation, lung transplantation, end stage renal disease on dialysis, cystic fibrosis, Down syndrome, mental disability and active lung disease as well as older age, using immunosuppressive medicines and oral corticosteroid therapy, and increased number of comorbidities. The Committee noted that this study was conducted in a pre-Omicron variant era and considered that the risk of hospitalisation and death has decreased in the Omicron era. The Committee also considered it reasonable to assume that these groups would still be at the highest risk of COVID-19 hospitalisation and death.

9.21. The Committee noted an analysis from Manatū Hauora - Ministry of Health on the risk of hospitalisation and death associated with COVID-19 for people aged under 70 years receiving DSS services funded by Whaikaha - Ministry of Disabled People, which reported a four times age-standardised rate of hospitalisation and 13 times crude risk of death compared to the rest of the population aged under 70 years (Ministry of Health. 2022. COVID-19 Risk Among Disabled People. Wellington: Ministry of Health). The Committee considered that those receiving DSS funding are a vulnerable, high need group made up of people with varying intellectual or physical disabilities. The Committee considered that the data for the risks of hospitalisation and mortality was not generalisable to all disabled people in New Zealand.

9.22. The Committee considered that those living rurally likely had a higher risk of severe COVID-19, but this was not quantifiable. The Committee noted that, in general, rural communities have a higher proportion of Māori, are demographically older, are associated with geographical areas of higher socioeconomic deprivation and have greater difficultly accessing vaccines, all of which increase the risk of severe COVID-19 outcomes.

9.23. The Committee considered that there was no New Zealand data for the risk in undocumented migrants and asylum seekers, however, internationally this group has a higher risk of poor outcomes from COVID-19 (Mengesha et al. Int J Environ Res Public Health. 2022;19:6624).

9.24. The Committee considered that front-line healthcare workers are protected by the use of personal protective equipment (PPE) and other infection control measures used in healthcare settings, hence they are more likely to catch COVID-19 from household exposure than in their healthcare setting. The Committee considered front-line healthcare workers using PPE correctly, routinely and consistently, is not a group that, at this point, seems to be at higher risk from occupational exposure.

9.24.1. The Committee noted the importance of vaccination, PPE use and other infection control measures in front-line healthcare workers to prevent them inadvertently exposing very vulnerable patients to COVID-19 (when workers infectious but pre-symptomatic) if workers became infected from elsewhere.

9.25. The Committee considered that COVID-19 disproportionally affects Māori, Pacific peoples, older people, people living in areas of high socioeconomic deprivation, those who are not vaccinated against COVID-19, pregnant people with comorbidities, disability, people with serious mental health conditions and/or drug addiction and those with chronic medical conditions. The Committee considered that the evidence for these needs is strong for age, vaccination status, deprivation, ethnicity, and immunocompromised, but that other potential groups would require international data and extrapolation of this data, to bridge the gaps where New Zealand data is lacking (eg utilising the Semenzatro et al. 2022 observational data for France to prioritise specific high risk comorbidity groups).

9.26. The Committee considered that the health need of people currently funded for vaccination was not equal and that the priority groups outlined above should be prioritised for future funding. The Committee considered that emerging COVID-19

variants mean that the risk for individual groups is likely to change particularly with absolute risk of hospitalisation and death decreasing with more recent emerging COVID-19 variants.

9.27. The Committee considered that booster vaccination of older people and people who are severely immunocompromised should have highest priority. The Committee considered that the priority for booster vaccination should be in the following order:

9.27.1. older people and people who are severely immunocompromised; then

9.27.2. under-vaccinated people (people who have not received a full primary course including a booster vaccination); then

9.27.3. Māori and Pacific peoples; then

9.27.4. disabled people; then

9.27.5. people with important comorbidities (particularly multiple comorbidities), people who are immunocompromised, and people with mental health conditions and drug addiction; then

9.27.6. people experiencing high socioeconomic deprivation (including community services card (CSC) holders); then

9.27.7. people who are pregnant (particularly those of Māori or Pacific ethnicity, and those with comorbidities and those who are under-vaccinated within this group).

9.28. The Committee considered that people with comorbidities that increased their risk of severe COVID-19 were well represented in the funding criteria for influenza vaccine, including people with serious mental health conditions and those experiencing drug addiction.

9.29. The Committee noted that vaccine uptake has decreased over time, with differences noted between ethnicities and age groups. The Committee considered that overall vaccine uptake was less relevant in the context of booster vaccination and recommending priority groups for funding.

*Health benefit*

9.30. The Committee noted international criteria for funded COVID-19 booster vaccinations from Australia, England and Wales and the United States. The Committee noted that recommendations from the Australian Technical Advice Group on Immunisation are for boosters for all people 65 years and older and people 18-64 years with complex medical comorbidities that increase their risk of severe disease. The Committee noted that booster vaccination of people under 18 years with no risk factors is not recommended and people who are 18-64 years with no other risk factors or people 5-17 years with complex health needs can consider booster vaccination. The Committee considered that these criteria were from early 2023 and COVID-19 disease environment may have changed in this time.

9.31. The Committee noted that the criteria in the United Kingdom were aiming to reduce the burden on health services over winter. The Committee noted that populations were prioritised by the Joint Committee on Vaccination and Immunisation based on this and booster vaccination was recommended for frontline health and social services, carers and staff in care homes, older or frail people, people with comorbidities and close contacts of immunosuppressed people 12-64 years old. The Committee noted that the relative prioritisation of groups was based on risk of severe COVID-19 outcomes with people living and working in care homes being of the highest priority and then by decreasing age and high-risk medical conditions.

9.32. The Committee noted that based on advice from by the National Advisory Committee on Immunisation, Health Canada recommended booster vaccination before winter for higher risk groups including: 65 years or older, residents of long-term care homes and other congregate living situations; those with underlying medical conditions that increase risk; pregnant people; people in or from First Nations, Métis and Inuit communities; members of racialised and other equity-deserving communities; and people who provide essential community services.

9.33. The Committee noted that CDC in the United States recommended that booster vaccination be discussed by the individual with their medical professional for anyone 12 years and over.

9.34. The Committee considered that the benefit of vaccination was derived from both the ability to produce antibodies and the cellular response to the antigen. The Committee considered that the correlation of antibody production and protection from severe disease was unknown. The Committee considered that protection is more effective for severe disease but antibody titres wane over time. The Committee considered that the T-cellular response wanes slower than the antibody response and so there is some continued protection after antibodies have waned.

9.35. The Committee considered that adults younger than 60 years have the highest level of protection due to hybrid immunity (vaccination and wild infection). The Committee considered that based on currently available information for those under 50 years, protection would last over 9 months and 4-6 months in older people. The Committee considered that people who are immunocompromised, have cancer or are very elderly, are less likely to produce sufficient antibodies or cellular response to vaccination, which may require more frequent vaccination for continued protection.

9.36. The Committee considered that protection against hospitalisation was high for three to six months in high-risk groups. The Committee considered that protection against severe disease wanes from six months onwards and the decline in protection after six months was mostly seen in people over 65 years and those with clinical risk factors for severe disease.

9.37. The Committee considered that it was currently appropriate to continue with six monthly booster vaccinations, with flexibility to have more frequent booster doses in people in higher need who are likely to respond sufficiently. The Committee considered that changes in the COVID-19 variant environment and seasonality of COVID-19 would mean that the frequency of boosters would need to be reviewed.

9.38. The Committee considered that heterologous vaccination with different vaccine platforms alongside infection (symptomatic or asymptomatic) with Omicron variants, provides broader, longer lasting protection than repeated vaccination with a single vaccine alone.

9.39. The Committee considered that continued vaccination of all people included in the currently funded groups was burdensome for the health system and community due to the large size of the group eligible for funding. The Committee considered that the funding criteria for who is eligible for booster vaccinations has been confusing, and the changing messaging over the pandemic period has contributed to the decrease in booster vaccination uptake. The Committee considered that it may be appropriate to align COVID-19 vaccination and influenza vaccination funding eligibility criteria to increase uptake and reduce the confusion for vaccinators and the public regarding who is eligible for a funded booster vaccine.

*Funding criteria*

9.40. The Committee considered that people who should be prioritised for funded booster vaccination include:

9.40.1. Older people (specifying age and Māori and Pacific peoples' lower age eligibility) and those living in residential care homes

9.40.2. People who have not received a full primary course, including a booster vaccination

9.40.3. Māori and Pacific peoples

9.40.4. Disabled people (including people who are DSS recipients)

9.40.5. People with comorbidities particularly people who are immunocompromised and those with mental health conditions and drug addiction

9.40.6. People experiencing high deprivation (including community services card holders (CSC) and people living in quintile 5 areas)

9.40.7. People who are pregnant.

9.41. The Committee considered that adult groups proposed for funding of COVID-19 booster vaccination should be aligned with the influenza vaccination comorbidities outlined.

9.42. The Committee considered that vaccination uptake in those who are pregnant has been historically poor. The Committee considered that not including pregnancy as a criterion may cause confusion and may also further reduce the uptake of vaccination in a group of people who are at increased risk of COVID-19 eg Māori and Pacific peoples or people with comorbidities who are pregnant.