Record of the Immunisation Advisory Committee Meeting held on 2 March 2023

Immunisation Advisory Committee records are published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) 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.

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1. Attendance

Present
Chair – Stephen Munn
Gary (Edwin) Reynolds
Karen Hoare
Lance Jennings
Michael Tatley
Nikki Turner
Osman Mansoor
Stuart Dalziel
Tony Walls

Apologies
Elizabeth Wilson
Giles Newton-Howes

2. Summary of recommendations

Pharmaceutical and Indication	Recommendation
• Fluzone high dose quadrivalent influenza vaccine (HD-QIV)	No change
• Hexaxim	No change

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) and Specialist Advisory Committees 2021, available on the Pharmac website at https://pharmac.govt.nz/assets/2021-Specialist-Advisory-Committee-Terms-of-Reference.pdf. The 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 7.2 of the PTAC 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 treatments for immunisation.

4. Record of Immunisation Advisory Committee meeting held Friday, September 9, 2022

4.1. The Advisory Committee reviewed and accepted the record of the Immunisation Advisory Committee meeting held on Friday 9 September 2022. The Committee noted that two correspondence items from suppliers about the previous record will be discussed at this meeting.

5. Previous action points/recommendations made

5.1. The Advisory Committee reviewed and noted the record of the PTAC meeting held on Friday 18 November 2022. The Committee noted that PTAC requested it to provide further rationale for the low priority recommendation for funding zoster vaccine for Māori and Pacific Peoples 60 years of age and over, and that it consider whether it would like to revise the priority of the recommendation made at its 9 May 2022 meeting.

5.2. The Committee considered that in general, immunisation programmes that target eligibility to specific groups, considered at higher risk of a disease or poor outcome, may not be easy to implement as part of a national programme. In many cases greater coverage of the target group may be achieved by a programme with universal eligibility. The Committee considered that the discussion and recommendations made at its May 2022 meeting centred around this consideration.

5.3. The Committee deferred making any changes to its previous recommendations until after it had reconsidered the data at a future meeting.

6. Correspondence and Matters Arising

Supplier correspondence – Fluzone high dose quadrivalent influenza vaccine (HD-QIV)

Recommendation

6.1. The Committee noted correspondence from the supplier of Fluzone high-dose influenza vaccine regarding the September 2022 Immunisation Advisory Committee record and recommended that no changes be made to the record.

Background

6.2. The Committee noted that in September 2022 it reviewed an application for listing Fluzone high-dose quadrivalent influenza vaccine (HD-QIV) in the Pharmaceutical Schedule for seasonal influenza vaccination for people aged 65 years and over, and for Māori and Pacific peoples aged 60 years and over.

6.3. The Committee noted that the supplier of Fluzone HD-QIV (Sanofi) wrote to Pharmac regarding the recommendations and details in the meeting record relating to Fluzone HD-QIV at the September 2022 meeting. The Committee noted that prior to the current meeting, Pharmac staff temporarily withheld some parts of the record from publication, on the understanding that the Committee would have the opportunity to review the supplier's comments on the record and provide clarifications at its next meeting.

Discussion

6.4. The Committee noted the following paragraph from the September 2022 meeting record:

"The Committee noted that there was more evidence available for the appraisal of Fluad Quad than there was for Fluzone high dose. The Committee considered that

while there was more evidence for the adjuvanted vaccine, it was primarily indirect comparisons, and that the strength of evidence for the two vaccines differed."

The Committee considered that the PICO table detailed in the September 2022 meeting record clearly states its advice: that standard dose quadrivalent influenza vaccine is the appropriate comparator for the New Zealand context. The Committee noted that the mention of Fluad Quad was not a part of the formal recommendation for Fluzone HD-QIV, but rather an explanatory note where the Committee has commented on its rationale for the different priority given to its recommendations for adjuvanted quadrivalent influenza vaccine (aQIV) and HD-QIV vaccines. The Committee considered that this section of the record accurately reflected its view.

6.5. At its September 2022 meeting, the Committee noted *that "there was more evidence available for the appraisal of Fluad Quad than there was for Fluzone high dose. The Committee considered that while there was more evidence for the adjuvanted vaccine, it was primarily indirect comparisons, and that the strength of evidence for the two vaccines differed."* The Committee considered that this excerpt reflected its opinion about the quantity and strength of evidence it had reviewed for Fluad Quad at its May 2022 meeting.

6.6. The Committee noted that, at its September 2022 meeting, it considered that either Fluad Quad or Fluzone HD-QIV would be appropriate for the elderly population, and that it had no preference between the two vaccines. The Committee considered that the comments relating to the evidence for the vaccines related to both the quantity of evidence it reviewed (which was greater in quantity for Fluad Quad), and that Fluad Quad has more randomised controlled trial data available than Fluzone HD-QIV. The Committee considered this excerpt accurately recorded its opinion.

6.7. The Committee considered the following paragraph from the September 2022 meeting record:

"The Committee considered the strength and quality of evidence to be moderate to weak and primarily observational but noted that for influenza vaccine trials it is unlikely that higher quality randomised controlled trial data would be feasible."

The Committee considered that this statement does not imply that there are no randomised controlled trials for Fluzone HD-QIV. The Committee considered that this statement is rather a comment on the lack of direct randomised controlled trial evidence against the New Zealand comparator (standard dose QIV). The Committee noted that there were immunogenicity measures reported but no direct comparisons of HD-QIV with SD-QIV in a randomised controlled trial for efficacy outcomes in the additional reference provided by the supplier. The Committee considered this excerpt accurately recorded its opinion.

6.8. The Committee considered the following paragraph from the September 2022 meeting record:

"The Committee noted that the Australian Technical Advisory Group on Immunisation (ATAGI) states in their 2022 guidance document that there is no preference for use between either Fluad Quad or Fluzone High Dose Quadrivalent in the 65+ age group, and that either is preferred over a standard dose vaccine for this age group. The Committee noted that there are no head-to-head trials between these two vaccines."

The Committee noted that it was aware of the other international recommendations described in the application but had chosen to specifically comment on the ATAGI 2022 guidance document which it considered of particular interest and relevance to New Zealand. The Committee considered this excerpt reflected its discussion at the meeting.

Supplier correspondence - Hexaxim

Recommendation

6.9. The Committee noted correspondence from the supplier of Hexaxim regarding the September 2022 Immunisation Advisory Committee record and recommended that no substantive changes be made to the record but suggested some minor clarifications.

Background

6.10. The Committee noted that in September 2022 it considered a data update for diphtheria, haemophilus influenzae type B, pertussis, tetanus, polio, hepatitis B (DTaP-hepB-IPV-Hib) vaccine (Hexaxim). The Committee noted that it recommended that consideration of the appropriateness of any change of the funded hexavalent vaccine to Hexaxim be deferred until data regarding Hexaxim efficacy against pertussis disease is available, as well as real world observational data on the reactogenicity and immunogenicity of concomitant administration with meningococcal B vaccine (Bexsero).

6.11. The Committee noted that it considered it would be clinically appropriate for DTPa-hepB-IPV-Hib (Hexaxim) to replace Infanrix Hexa in the childhood Immunisation Schedule provided that immunisation rates were at 95% or greater, but not at the present time based on current immunisation rates.

6.12. The Committee noted that the supplier of Hexaxim (Sanofi) wrote to Pharmac regarding the recommendations and details in the meeting record relating to Hexaxim at the September 2022 meeting. The Committee noted that prior to the current meeting, Pharmac staff temporarily withheld some parts of the record from publication, on the understanding that the Committee would have the opportunity to review the supplier's comments on the record and provide clarifications at its next meeting.

Discussion

6.13. The Committee noted that DT3aP-HBV-IPV/Hib (Infanrix Hexa) is currently funded for children up to 10 years and up to four or five doses for children following immunosuppressive regimens (eg due to haematopoietic stem cell transplant, solid organ transplant or chemotherapy). The Committee noted that the current vaccination schedule is 3+0 at 6 weeks, 3 months and 5 months with an additional pertussis containing DTaP booster dose at 4 years. The Committee noted that there is not currently a pertussis-containing vaccine given in the second year of life. The Committee noted that both Hexaxim and Infanrix Hexa contain pertussis filamentous Haemagglutinin (FHA) 25 mcg and pertussis toxoid (PT) 25 mcg, however, Infanrix Hexa also contains pertactin 8 mcg as a third pertussis antigen.

6.14. The Committee noted that immunisation rates against pertussis have been decreasing for some years in the childhood programme, and noted with concern that there are also very low coverage rates for pregnancy vaccination and significant inequities in vaccination coverage, with Māori and Pacific children disproportionately affected. The Committee noted that in 2022, immunisation rates at 6 months of age, which is a measure of achieving timely delivery by one month after the third infant dose, ranged from 67.2%-68.7% for all tamariki, and 45.9-49.3% for Māori tamariki.

6.15. The Committee considered that it was unclear what effect, if any, a change from 3aP to 2aP would have on the emergence of vaccine-evasive/resistant strains of pertussis, but again noted evidence that vaccine-evasive or resistant strains (especially pertactin deficient strains) are emerging. Members considered that the globally increasing circulation of these strains may be due to the use of acellular pertussis (aP) in vaccines, and that those vaccinated with aP are more susceptible to pertactin deficient

strains. The Committee considered it was not aware of any data describing whether pertactin deficient strains were currently circulating in New Zealand.

6.16. The Committee considered the following paragraph from the September 2022 meeting record:

"The Committee was made aware of data extracted from the WHO Immunisation Data portal in September 2022, reporting low incidence of pertussis infection in Sweden and in Belgium, each with over 97% vaccine coverage using two component (2aP) and/or three component (3aP) acellular pertussis vaccines and either 2+1 (Sweden) or 3+1 (Belgium) dosing schedules. The Committee considered this was not comparable to New Zealand given the differences in pertussis epidemiology.

The Committee noted that Belgium and Sweden both have pertussis vaccination coverage over 90%, using either 3+1 or 2+1 vaccination schedules. The Committee also considered Sweden and Belgium do not have the same high peaks of pertussis cases that are periodically seen in New Zealand. The Committee considered that immunisation coverage was much higher during the last pertussis "peak" in New Zealand, so the current low immunisation coverage rates increase the risk that an outbreak with more severe disease in young infants might occur. The Committee considered that this reflects its discussion at the September 2022 meeting and is relevant to identify that the New Zealand epidemiology differs from other studied populations, which is important contextual information.

6.17. The Committee considered the following paragraph from the September 2022 meeting record:

"The Committee considered that the evidence for Hexaxim was of low to moderate strength and quality, coming from high quality well-designed randomised controlled trials. However, the Committee noted the trials were not blinded (which was considered understandable in this context), did not include New Zealand participants, used different dosing schedules, and only used surrogate endpoints (for which an internationally accepted required level of protection correlating to surrogates is lacking) instead of providing direct evidence of efficacy against pertussis. The Committee considered that long term follow-up data for efficacy of 2aP compared with 3aP was absent, as was evidence of efficacy against pertussis during outbreaks or with less than 95% vaccine coverage."

The Committee noted that this excerpt was referring only to evidence considered at the September 2022 meeting, which focused on publications since 2015 and those in the clinical data update provided by the supplier. It was not intended as commentary on the totality of the body of evidence for Hexaxim.

6.18. The Committee suggested that this could be clarified if the record was amended to read as follows (additions in **bold**, deletions in ~~strikethrough~~):

*"The Committee considered that the evidence for Hexaxim **vs. 3aP** was of low to moderate strength and quality, coming from high quality well-designed randomised controlled trials. However, the Committee noted the trials were ~~not~~ **single** blinded (which was considered understandable in this context), did not include New Zealand participants, used different dosing schedules, and only used surrogate endpoints (for which an internationally accepted required level of protection correlating to surrogates is lacking) instead of providing direct evidence of efficacy against pertussis. The Committee considered that long term follow-up data for efficacy of 2aP compared with 3aP was absent, as was evidence of efficacy against pertussis during outbreaks or with less than 95% vaccine coverage."*

6.19. The Committee considered the following paragraph from the September 2022 meeting record:

"The Committee considered that Hexaxim's increased reactogenicity (compared with Infanrix Hexa) could result in increased cases of fever potentially resulting in presentations to Emergency Departments if it was included in the childhood immunisation schedule alongside Bexsero and if they were concomitantly administered. The Committee noted that there was an absence of evidence on concomitant administration to inform this consideration."

The Committee noted that this paragraph was temporarily withheld from publication pending further comment from the Committee, including on the additional data regarding the concomitant administration of Hexaxim with Bexsero.

6.20. The Committee again noted a recent meta-analysis (Knuf et al. Vaccine. 2021;39:6025-36 Committee noted that this meta-analysis reported that while individual studies concluded that both vaccines have acceptable safety profiles, the analysis of head-to-head trials showed that redness, pain, swelling, fever, persistent crying, irritability, drowsiness and anorexia were less frequent with DT3aP-HBV-IPV/Hib versus DT2aP-HBV-IPV-Hib. The Committee suggested that the record be amended to read as follows (additions in **bold)**:

"The Committee considered that Hexaxim's increased reactogenicity (compared with Infanrix Hexa, as reported in meta-analysis of published RCTs [***Knuf et al. Vaccine. 2021;39:6025-36***]) could result in increased cases of fever potentially resulting in presentations to Emergency Departments if it was included in the childhood immunisation schedule alongside Bexsero and if they were concomitantly administered. The Committee noted that there was an absence of evidence on concomitant administration to inform this consideration."

The Committee also noted that the supplier had conducted its own meta-analysis on individual patient data, using data from clinical databases (Vargas-Zambano et al. 2022; Abstract ISOPR Abstract only) and that there is an ongoing supplier-sponsored study A3L00057 titled 'Immunogenicity and Safety of DTaP-IPV-HB-PRP~T Combined vaccine Given at 3, 5, and 12 Months of Age Concomitantly or Sequentially with 4CMenB Vaccine in Italian Infants'. The Committee considered that this study would be very relevant, but it would be appropriate to await published, peer-reviewed manuscripts of these studies as any difference in incidence of febrile convulsions and fever between the 2aP and 3aP vaccines would have considerable impacts on the health system resource.

6.21. The Committee considered the following paragraphs of the September 2022 record pertaining to the availability of efficacy data for Hexaxim against pertussis disease:

"The Committee recommended that consideration of the appropriateness of any change to DTPa-hepB-IPV-Hib (Hexaxim) through any vaccines commercial process be deferred until data regarding DTPa-hepB-IPV-Hib (Hexaxin) efficacy against pertussis disease is available, as well as real world observational data on the reactogenicity and immunogenicity of concomitant administration with meningococcal B vaccine (Bexsero)."

"On balance, the Committee considered it would be clinically appropriate for DTPa-hepB-IPV-Hib (Hexaxim) to replace Infanrix Hexa in the childhood immunisation schedule provided that immunisation rates were at 95% or greater, but not at the present time based on current immunisation rates. The Committee considered that the consideration of the suitability of any change from Infanrix Hexa to Hexaxim on the childhood immunisation schedule should be deferred until direct evidence regarding Hexaxim efficacy against pertussis disease is available (and evidence of concomitant

administration with the meningococcal B multicomponent vaccine Bexsero [real world, observational data of safety and immunogenicity], if it becomes available)."

6.22. The Committee noted that the supplier referenced a 1997 study comparing a two-component acellular to a whole-cell pertussis vaccine in Senegal relating to efficacy of the 2aP antigens contained in Hexaxim (Simondon et al. Vaccine. 1997;15:1606; Appendix 2), a Swedish effectiveness study (Aronsson et al. 2020. ESPID Virtual meeting) and a Mexican effectiveness study (Aquino et al. Vaccine. 2012;30:6492-500) as further evidence. The Committee considered that it was important to consider the impact of changing vaccines in the scenario when vaccination rates are low, as without a meaningful change for efficacy, any increase in circulating infection could increase the risk of children, particularly infants, developing severe disease. The Committee noted that non-inferiority between the 2aP and 3aP vaccines was established for surrogate endpoints with high quality randomised controlled trials, but the Committee reiterated its view that there were no high-quality studies reporting the efficacy of 2aP compared with 3aP vaccine for clinical pertussis. The Committee considered this is particularly relevant at this time when the incidence of pertussis disease in New Zealand is expected to peak again, based on historical evidence of disease fluctuations over time and current low rates of vaccination.

6.23. The Committee considered that the record be amended to read as follows (additions in **bold**):

"The Committee recommended that consideration of the appropriateness of any change to DT**2**Pa-hepB-IPV-Hib (Hexaxim) through any vaccines commercial process be deferred until data regarding DT**2**Pa-hepB-IPV-Hib (Hexaxim) **vs. DT3Pa-hepB-IPV-Hib** efficacy against pertussis disease is available, as well as real world observational data on the reactogenicity and immunogenicity of concomitant administration with meningococcal B vaccine (Bexsero)."

"On balance, the Committee considered it would be clinically appropriate for DT**2**Pa-hepB-IPV-Hib (Hexaxim) to replace Infanrix Hexa (**DT3Pa-hepB-IPV-Hib**) in the childhood immunisation schedule provided that **infant** immunisation rates **at one year of age** were at 95% or greater, but not at the present time based on current immunisation rates. The Committee considered that the consideration of the suitability of any change from Infanrix Hexa to Hexaxim on the childhood immunisation schedule should be deferred until direct evidence regarding Hexaxim vs. **DT3Pa-hepB-IPV-Hib** efficacy against pertussis disease is available (and evidence of concomitant administration with the meningococcal B multicomponent vaccine Bexsero [real world, observational data of safety and immunogenicity], if it becomes available)."

7. Pneumococcal – Epidemiology update

7.1. The Advisory Committee reviewed the updated epidemiological data for invasive pneumococcal disease for New Zealand from July to September 2022.

7.2. The purpose of the discussion was to review the epidemiology of invasive pneumococcal disease following the decision in 2022 to change the pneumococcal vaccine used in the infant immunisation schedule from PCV10 to PCV13.

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

Discussion

Māori impact

7.4. The Committee noted that invasive pneumococcal disease disproportionally affects Māori children, particularly through the increased burden of disease associated with the rise in 19A cases.

Background

7.5. The Committee noted that since the last consideration of invasive pneumococcal disease there had been a change in the vaccine schedule.

7.6. The Committee noted that the vaccine schedule has been amended over time:

- June 2008: Schedule changed from PCV7 to PCV10, except in high-risk who would receive PCV13.
- July 2014: Schedule amended to PCV13 only. Change was made with the aim to protect against more serotypes.
- July 2017: Schedule amended for all to receive PCV10 except high risk who would receive PCV13. Change was made with the assumption that coverage of 19F would offer cross-protection against 19A.
- December 2022: Schedule amended to PCV13 only. Change was made to address the rising incidence of serotype 19A cases.

7.7. Upon switching to PCV10 vaccine in June 2008 the Immunisation Advisory Committee recommended the monitoring of the incidence of serotype 19A to inform of any need to amend the Schedule as necessary. Upon advice from PTAC in February 2022 and the Immunisation Advisory Committee in April 2022, Pharmac accordingly widened access to PCV13 from 1 December 2022 to list it in the Pharmaceutical Schedule with a 2+1 dosing schedule for children under 5 years of age.

7.8. The Committee noted that during the period where PCV13 was only available for high-risk children it is estimated that fewer than 5% of children classified at high-risk were vaccinated with PCV13, with the majority receiving PCV10. The Committee considered this is partly why in many cases it prefers a universal vaccination policy that does not differentiate on the basis of perceived clinical need, geography or ethnicity.

7.9. The Committee noted from the ESR report that most cases of invasive disease in children aged under 2 in 2021/22 would not have qualified for PCV13 under the previous high-risk scheme.

Health need

7.10. The Committee considered that pneumococcal disease has a high global burden of mortality and morbidity. The Committee noted that there were more than 90 identifiable serotypes of Streptococcus pneumoniae, with certain serotypes more invasive than others, as well as serotypes which are more antibiotic resistant.

7.11. The Committee has previously considered that that invasive disease such as meningitis, bacteraemia, and bacteraemic pneumonia significantly impact the individuals affected, as well as their family/whānau and society. The Committee considered that pneumococcal infection can also result in non-invasive disease (eg non-bacteraemic pneumonia and acute otitis media) that creates an additional burden and high health need.

7.12. The Committee considered the differing immunisation programmes in other countries, including Belgium, Brazil, and Colombia. The Committee noted that very few regions globally have switched from PCV13 back to PCV10. The Committee considered the Desmet et al, Lancet Infect Dis, 2018;18:945-946 study based in Belgium that showed

a 10-fold increase in 19A cases in children under 2 years of age after switching back to PCV10. There were particular concerns as 19A is a common serotype in Belgium and one of the most antibiotic resistant serotypes. The Committee noted that similar trends have also been observed in other countries that switched, including Sweden.

7.13. The Committee noted the study Agudelo et Lancet Infect Dis. 2021 Mar;21:405-417, which described the trend of the additional PCV13 serotypes in children under 5 years of age in Brazil and Colombia, where PCV10 is used. The study showed an increase in the 19A serotype since 2015.

7.14. The Committee considered data from Hagedoorn et al, PD132, 40th Meeting, ESPID 2022 and the Institute of Environmental Science and Research (ESR) Invasive Pneumococcal Disease in New Zealand Surveillance Report 2011, that showed rates of disease per 100,000 in New Zealand, in those under the age of 2 years, have reduced since 2006. More specifically from 100 cases per 100,000 to between 20-40 per 100,000 from 2017 to 2021.

7.15. The Committee noted data from Hagedoorn et al, PD132, 40th Meeting, ESPID 2022 that compared rates of invasive pneumococcal disease between New Zealand and Australia in those under than 2 years of age between 2017 and 2021. The Committee noted that Australia used PCV13 throughout the time period. The Committee noted that rates of disease did not differ between the two countries until 2021, where the rates of disease were higher in New Zealand (37.4; 95% CI 27.3-50.0) compared with Australia (24.7; 95% CI 20.9-29.0) (p=0.02). Rates of serotype 19A increased in New Zealand to account for between 30-40% of all cases, whilst remaining below 10% in Australia. The Committee noted that serotype 19A was not covered by the PCV10 vaccine available in New Zealand at that time, except in high-risk people who were eligible to receive the PCV13 vaccine.

7.16. The Committee considered an ESR report with an updated summary of the epidemiology of invasive pneumococcal disease in New Zealand between July and September 2022. The data cut off point for the reported data was 1 October 2022.

7.16.1. The Committee noted the rate per 100,000 of invasive pneumococcal disease from 2011 to Quarter 3 2021, by age group, and by era of funded PCV vaccine. The Committee noted that the annual rate of invasive pneumococcal disease, albeit with some fluctuations, has continued to trend down over time. The Committee noted that there were likely to be effects on the 2020 data from the COVI-19 pandemic, and introduction of associated wider public health measures in New Zealand from early 2020, with 29% fewer invasive pneumococcal disease cases notified in 2020.

7.16.2. The Committee noted that the rates in the 0-2 years and 2-4 years age group have been increasing since 2022. The Committee noted that the number of cases in those under 2 years of age was the highest rate since the disease had been notifiable.

7.16.3. The Committee noted the quarterly rates of invasive pneumococcal disease, which showed a total of 246 cases of invasive pneumococcal disease were notified from July to September 2022, which was the highest rate in any Quarter 3 since rates were notifiable (n=254 cases in Quarter 3 2009).

7.16.4. The Committee noted the total number of invasive pneumococcal disease by age group and district showing that the Northern Region had the highest number of invasive pneumococcal disease cases notified of any serotype each year through to September (n=181 in 2022). The number of children under 5 years diagnosed with invasive pneumococcal disease in the Northern Region (n=31) has increased by 50% since 2021 (n=22) and is the highest number reported in this age group since invasive pneumococcal disease

became notifiable. The highest number of 19A cases have been notified in the Northern Region. The number of 19A cases has increased by 30-115% in all regions, except the Midland Region in 2022, as compared to 2021. The number of 19A cases in children under 5 years has increased by 50% in the Northern Region, and 2- to 3- fold higher in the Midland and Central regions (though numbers are small), compared to 2021.

7.16.5. The Committee noted the rates of invasive pneumococcal disease, in children under the age of 2, for the 12 months preceding 30 September 2022, that were of serotype 19A compared to serotype 3, 6A and 19A combined. The Committee noted that there was concern over the rate of 19A infections, and that the threshold set by ESR for 19A (9.1 per 100,000 children less than 2 years of age) was reached in Quarter 2 2021 at 13.3 cases per 100,00. This continued to increase to 17.4 cases per 100,000 in Quarter 3 2021. In the 12 months ending September 2022, the rate of 19A cases reached a record high to date, with 23.3 cases per 100,000.

7.16.6. The Committee noted the annual rate of 19A by age group, and PCV era, from 2011-2022 showed an increase in serotype 19A cases for children under 2 years of age, and children aged 2-4 years from 2017 to 2021 after the change back to PCV10 from PCV13.

7.16.7. The Committee noted the number of invasive pneumococcal disease cases in those under 5 years of age, that were preventable with either PCV10, or that had PCV13 serotypes, and the number of those that were of serotype 19A. The Committee noted that invasive pneumococcal disease cases had increased from 45 in 2017 to 72 in 2022. The number of PCV10 vaccine preventable cases was low, with one or less per year since 2018. The number of cases of 19A serotype has increased over time, from 4 (36.4%) to 49 (96.1%) from 2017-2022.

7.16.8. The Committee noted the year-to-date serotype 19A cumulative totals by year and age group. The Committee noted that in those under the age of 2 years, the number of cases increased from 3 (7% of total cases in this age group) to 28 (16.9%) from 2019 to 2022.

7.16.9. The Committee noted that all cases had severe disease, with those with invasive pneumococcal disease hospitalised. The Committee noted that cases of mastoiditis, as well as streptococcus pneumoniae-associated haemolytic uremic syndrome, had increased.

7.16.10. The Committee considered data of the vaccination status of all children eligible for PCV who were born after 1 January 2008, of which 78 children were diagnosed with invasive pneumococcal disease up to the end of Quarter 3 2022. Of these 78 children, 68 had National Immunisation Register (NIR) data available and 10 had no NIR data and were assumed to be unvaccinated. Of these 78 children, 66.7% (n=52) had serotype 19A disease, 2.6% (n=2) involved serotype 3, 1.3% (n=1) cases were of serotype 9V, and 29.5% (n=23) involved non-PCV serotypes or were cases where the serotype is still unknown.

7.16.11. One case of invasive pneumococcal disease in an unvaccinated child was reported. This involved serotype 9V, a serotype covered by PCV7.There were two cases of IPD that were serotype 3, a serotype covered by PCV13. One child had received three doses of PCV10, and one child had received one PCV10 dose and three PCV13 doses.

7.16.12. The Committee noted that none of the 52 childhood cases of invasive pneumococcal disease involving serotype 19A, who were eligible for

vaccination, had been vaccinated with any doses of PCV13. Seven children were unvaccinated, one had received three PCV7 doses and one PCV10 dose, and one child had received four doses of PCV7. The remainder had been vaccinated with PCV 10 alone (19 had 1-2 doses, seven had received 3 doses, 17 had 4 doses). It is unknown whether these children were eligible to receive PCV13 due to having a high-risk condition. The Committee noted that no infections of serotype 19A occurred in children that had received the PCV13 vaccine, whilst many of those with 19A infections had received the PCV10 vaccine.

7.16.13. The Committee considered that the data supported the change from the PCV10 to PCV13 vaccine in the context of New Zealand epidemiology.

7.17. The Committee noted the need to respond to serotype prevalence changes with changes in the immunisation Schedule within a short time frame.

Health benefit

7.18. The Committee noted that it had previously noted that the risk of invasive pneumococcal disease for Māori is over three times higher than the risk for New Zealand Europeans (Immunisation Advisory Centre, 2020). The Committee (formerly the Immunisation Subcommittee) noted that it had previously considered that Māori are disproportionately affected by invasive pneumococcal disease, were over-represented in the 19A cases that occurred in 2020 in children under 5 years of age and are disproportionately affected by the increased burden of disease associated with the rise in 19A cases.

7.19. The Committee also noted that it had previously considered that risk of invasive pneumococcal disease for Pacific peoples is almost four times higher than the risk for New Zealand Europeans (Immunisation Advisory Centre, 2020). The Committee noted that it had previously considered that Pacific peoples were over-represented in the 19A cases that occurred in 2020 in children under 5 years of age, as well as the and the serotype 19A deaths in 2020-2021.

7.20. The Committee noted that it had previously considered that higher rates of invasive pneumococcal disease are also seen in populations living in more socio-economically deprived areas.

7.21. The Committee noted an increase in the number of 19A cases in those over 65 years of age, and the potential need for vaccination of this population with the PCV13 vaccine.

7.22. The Committee noted there was an increase in the proportion of 19A cases that were penicillin resistant. The Committee noted other pharmaceuticals were available to treat these cases.

Suitability

7.23. The Committee considered that that service delivery mechanisms for the COVID-19 pandemic vaccines could be reviewed to inform improved access to vaccination for higher priority groups who are disproportionately affected by invasive pneumococcal disease, such as Māori and Pacific peoples.

7.24. The Committee considered that universal vaccine programmes overall generally provide more equitable access to vaccines than targeting specific groups through eligibility criteria.

7.25. The Committee noted a funded PCV13 catch up programme for those aged under 5 who have previously only received PCV10 needs thorough investigation. This programme would need to account for whānau based strategies of delivery for Māori.

7.26. The Committee considered that it would like to consider pneumococcal disease in other groups, such as adults over 65 years of age, at a future meeting.

8. Meningococcal -Epidemiology update

Application

8.1. The Advisory Committee reviewed an update in relation to epidemiology of meningococcal infections in New Zealand.

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

Discussion

Māori impact

8.3. The Committee discussed the impact of meningococcal infections, and invasive meningococcal disease, on Hauora Arotahi - Māori health areas of focus and Māori health outcomes. The Committee noted that cases of invasive meningococcal disease in New Zealand in 2022 had occurred disproportionately in people of Māori ethnicity, with 49% of the cases occurring in Māori children under the age of 5 years.

8.4. The Committee considered that it was highly likely that socioeconomic status and household crowding were factors in the increased rates for this group of people.

Background

8.5. The Committee has previously considered meningococcal vaccination and several vaccines are currently funded by Pharmac for a range of eligible groups.

8.6. Advice from the Committee was sought regarding the updated meningococcal epidemiological data presented to the Committee.

Health need

8.7. The Committee noted that meningococcal disease is a bacterial infection caused by Neisseria meningitidis, a gram-negative bacterium, and is an important cause of sepsis and meningitis. The Committee also noted that more than12 groups of the bacteria have been identified with six serotype groups: A, B, C, X, Y and W.

8.8. The Committee noted that meningococcal disease in New Zealand is currently predominantly caused by meningococcal serogroups B, W and Y though prevailing strains can change rapidly over 1-2 winter seasons. The Committee noted that outbreaks of serogroups C and W have been reported in New Zealand previously.

8.9. The Committee noted clinical presentation can vary widely between serogroups eg serogroup W or Y with more abdominal symptoms in older age groups.

8.10. The Committee noted that transmission from person to person is by respiratory droplets, or direct contact with nasopharyngeal secretions, from a carrier or case, and infection can result in invasive meningococcal disease.

8.11. The Committee noted that people with invasive meningococcal disease can often initially present with nonspecific signs including fever, lethargy, irritability, nausea, and poor feeding and their clinical presentation rapidly progresses to three general disease patterns: clinical meningitis, meningococcal septicaemia or a combination of septicaemia and meningitis. Severe infection leads to shock, disseminated intra-vascular coagulation, acrocyanosis and multi-organ failure.

8.12. The Committee noted that invasive meningococcal disease had a fatality rate of 4-6% and had lifelong consequences for survivors and their whānau.

8.13. The Committee noted that long lasting effects from the disease include neurological sequalae including brain damage and hearing loss (approximately 10-20%). In addition, individuals can experience renal failure and disfigurement. The Committee considered the Olbrich et al, Infect Dis Ther. 2018;7: 421–438 study that reported long term effects from invasive meningococcal disease may include neurological symptoms including anxiety, learning difficulties, emotional and behavioural difficulties. In addition, the study reported that up to 8% of children undergo amputations, with 55% having skin scars.

8.14. The Committee noted that invasive meningococcal disease affects the health need of family, whānau, and wider society. The Committee considered the Olbrich et al, Infect Dis Ther. 2018;7: 421–438 study that reported invasive meningococcal disease negatively effects the health-related quality of life both in the short- and long-term.

8.15. The Committee considered the Shears et al. Pediatr Crit Care Med. 2005;6:39-43 study that studied paediatric intensive care unit (PICU) admissions for invasive meningococcal disease and reported that there was an increase in psychiatric and posttraumatic stress disorder in both children (mean age 6.8) and parents.

8.16. The Committee considered the Judge et al. Intensive Care Med. 2002;25:648-50 study that reported a large proportion of mothers of childhood invasive meningococcal disease survivors (mean child age 5.7) treated in the PICU had a high risk of experiencing ongoing psychological stress, with 29% seeking help for these problems at a mean of 8.9 months after discharge.

8.17. The Committee considered the Hareth et al. Health Econ. 2016;25:1529-44 study that reported that family members of invasive meningococcal disease survivors have long-term impacts on their health, with anxiety and depression which extended to the wider family.

8.18. The Committee noted that mortality and morbidity vary with serotype and further noted that meningococcal C disease is associated with a higher mortality than meningococcal B. The Committee noted that there have been no cases of meningococcal C disease reported in New Zealand since 2019.

8.19. The Committee noted the Invasive Meningococcal Disease Monthly Report November 2022 from the Institute of Environmental Science and Research (ESR) that reported the number of cases of invasive meningococcal disease per serotype that occurred between 2013 and 2022. The Committee noted that group B is the predominant serogroup in New Zealand. The Committee considered that group C used to account for up to 1 in 3 cases of invasive meningococcal disease, however this has now decreased, and is not as prevalent within New Zealand. group W cases peaked from 2017-2019, and have reduced since 2019, whilst cases of group Y have started to increase again in 2022.

8.20. The Committee noted that there has been a change in serotype dominance over time, and therefore the appropriate vaccine for preventing serotypes may also need to change over time. The morbidity and mortality of groups ACWY is more severe than group B, and therefore, it is important that vaccination includes protection against these groups. The Committee considered that an extension of the catch-up period to receive ACWY vaccine, especially in most at risk populations such as Māori, would improve vaccination coverage of these populations.

8.21. The Committee noted that New Zealand is a high-rate country for invasive meningococcal disease when considering the global context.

8.22. The Committee considered that it was important not to consider invasive meningococcal disease in isolation, and that a reduction in invasive meningococcal disease during the COVID-19 pandemic could be linked to a decrease in influenza and

respiratory syncytial virus infections. The Committee noted that seasonal trends in the number of cases remained, with peak numbers occurring in June and July, and continuing into spring.

8.23. The Committee noted that the ESR report stated that there were 69 confirmed cases of invasive meningococcal disease up to November 2022, and three deaths which occurred in two children aged <1 year and 1-4 years, as well as one in a young adult aged 15-19 years of age. One death was reported as due to group B, PorA type P1.7-2,4 which is the New Zealand epidemic strain.

8.24. The Committee noted the ESR report demonstrated that invasive meningococcal disease data disproportionately affected people of Māori ethnicity. The Committee noted that the report stated that 32 out of 69 cases (46%) were in Māori, with most cases in those under the age of 5 years (n=24), whilst three cases were notified in individuals 5–19-years of age, two cases in individuals between 20-29 years of age, and three cases in individuals 40–70 years of age. The Committee noted that a similar trend was also observed in Pacific peoples, where the majority of cases were in individuals under 4 years of age (n=6), and three cases observed in children aged between 5 and 19 years of age. One case was reported in an individual between 30-39 years of age. The Committee noted that people of European or Other ethnicity cases show a more bimodal distribution, with cases more likely to be reported in the 15-29 age range (n=10), and in individuals over 50 (n=8). Three cases were observed in children under the age of 14, and two cases between 30-49 years of age. The Committee noted that the risk in children of Pacific ethnicity who are under the age of 1 is high.

8.25. The Committee considered that deprivation index is a good indicator of risk for meningococcal disease and could be an alternative to ethnicity-based eligibility criteria to identify those most at risk of meningococcal disease.

8.26. The Committee noted that there was an increase in group Y disease in those of an older age group (>70 years of age), with three cases reported in those of a European or other ethnicity.

8.27. The Committee noted that meningococcal cases are geographically dispersed, with the majority of cases found between Northland and Taranaki, with 40/69 cases reported in this region. The serotypes of the northern cases were determined to be group B in 27/40 cases, two were group W, and one was group Y. Seven cases were of an unknown group, and three were not able to be confirmed by a laboratory. Nine cases were reported in the Southern district of the South Island (n=9/69). The serotype of the cases notified from the Southern district were split between group B and group Y (n=4 each), with one case additionally notified where the group was unknown. No cases of group C or E associated disease were reported.

8.28. The Committee noted that the majority of cases reported of unknown group involved children under the age of 5 years.

8.29. The Committee noted that group B case numbers had decreased during the pandemic, in 2020 and 2021, and had increased again in 2022 to pre-pandemic levels.

8.30. The Committee noted the number of meningococcal B disease cases by ethnicity and age group (January-11 November 2022) reported by ESR. The Committee noted that the distribution of cases was bimodal, with group B cases mainly in those under the age of 5 years of age, and between 15-19 and 20-29 years of age. (There was also a slight increase in those aged 60-69 years old).

8.31. The Committee considered data from the number of cases of invasive meningococcal disease to date in 2023. The Committee noted that until the week ending the 17th of February 2023, five cases had been reported, with no deaths. The Committee further

noted that a total of 72 cases of invasive meningococcal disease were reported in 2022, with a total of three deaths.

8.32. The Committee noted that those who are immunocompromised have an increased risk from meningococcal disease this included people who are living with HIV, those who are undergoing chemotherapy, have planned immunosuppression, or who have undergone splenectomies or haemopoietic stem cell transplants.

8.33. The Committee considered individuals who lived in shared living accommodation, including prisons, boarding schools, or hostels to be at an increased risk. The Committee also considered the Dubey et al, Int J Infect Dis. 2022;119:1-9 study that reported those who lived in overcrowded housing or are exposed to passive smoke to be at an increased risk.

Health benefit

8.34. The Committee noted group B cases, stratified by PorA types reported by ESR. The Committee noted that the majority of meningococcal cases reported in 2022 involved group B meningococci (n=45/69). The Committee noted that there were currently 14 PorA types, and the most prevalent PorA types were B: P1.7-12,14 (n=14) and B:P1.7-2,4 (the 1991–2007 New Zealand epidemic strain) (n=14). The Committee considered that there was a significant increase in the relative proportion of B: P1.7-12,14 within the group B meningococci detected from 2013 to November 2022. The Committee noted that whole genome sequencing has identified the strain is the clonal complex ST-1572, which is relatively rare internationally.

8.35. The Committee considered that there was insufficient evidence to know if Group B PorA types may affect the efficacy of the 4CMenB vaccine, however considered that funding the 4CMenB vaccine continued to be appropriate. The Committee considered that the Trumenba brand vaccine would not be suitable for use in New Zealand at present as it is not approved for use in children under 10 years of age and does not contain any antigen for the New Zealand epidemic strain.

8.36. The Committee considered that meningococcal immunisation programmes in the UK, Netherlands, and Australia would be good comparators for New Zealand to assess what types of approach have been effective.

8.37. The Committee considered that herd immunity has been demonstrated for meningococcal group C, however, data is still emerging for groups A, W and Y. The Committee considered that there is no data showing herd immunity for group B, so immunisation for group B provides individual protection. The Committee considered that the lack of herd immunity effects has been demonstrated in a recent study about the meningococcal B programme in South Australia.

Suitability

8.38. The Committee noted that whānau based models of delivery have been established during the COVID-19 vaccine programme. The Committee considered that whānau based delivery systems require; extra time for consultation, building trust in the community but enable the whole family/ whānau to receive their vaccines together.

8.39. The Committee considered that catch-up periods of one year were too short for meningococcal immunisation programmes. The Committee considered that longer catch-up periods would be more effective, and improve coverage, by reducing barriers to accessing healthcare. The Committee also considered that it would be preferable to move away from time limited catch up programmes and instead fund vaccines for the whole age range. The Committee considered it likely that most vaccinations would still occur in the first 1-2 years of a programme, but there could be a long tail of hard-to-reach eligible people.

Cost and savings

8.40. The Committee noted that whānau based models of delivery would likely cost more to the health sector to implement but high coverage in those disproportionately affected by meningococcal disease, including Māori and Pacific peoples, would potentially be more cost effective for the health system longer term.

9. Vaccine RFP 2023

Background

9.1. The Advisory Committee considered a paper from Pharmac staff regarding the Request for Proposals for the supply of various vaccines and a diagnostic agent, outlining a number of possible changes to funded vaccines the could occur from July 2024 as a result of the RFP.

Discussion

Haemophilus influenzae type b vaccine

9.2. The Committee noted that the *Haemophilus influenzae* type b (Hib) component is included in the Pharmaceutical Schedule and National Immunisation Schedule at ages 6 weeks, 3 months and 5 months as part of the hexavalent vaccine. It is also included in the Schedule as a stand-alone vaccination at the 15-month milestone immunisation infant visit.

9.3. The Committee noted that the Hiberix brand is approved for use in infants from 6 weeks age and the Act-HIB brand is approved for use in infants from 2 months to 5 years of age. The Committee considered that as the stand-alone Hib booster dose is given at the 15-month milestone immunisation visit, the differences in the approved age ranges did not affect the suitability of these vaccines for use at 15 months of age. The Committee considered that either Hiberix or Act-HIB would be suitable for listing in the Pharmaceutical Schedule for a booster dose at 15 months of age.

Hepatitis A vaccine

9.4. The Committee noted that hepatitis A vaccine is listed in the Pharmaceutical Schedule for use in transplant patients, children with chronic liver disease and close contacts of cases of hepatitis A infection (one funded dose).

9.5. The Committee noted that the Havrix Junior brand is approved for use in children from 1 to 15 years of age and the Avaxim brand is approved for use in individuals from 2 years of age, but there is a need to use hepatitis A vaccine in the under 2 years of age cohort, especially amongst contacts of cases. The Committee considered that hepatitis A can occur in children less than 24 months of age. Particularly in managing a public health response, there would be health benefit gained from offering a vaccine that could be given to children between 12 and 23 months of age who were close contacts of known hepatitis A cases.

Measles, mumps and rubella (MMR) vaccine

9.6. The Committee noted that the MMR vaccine is funded for primary vaccination in children, revaccination following immunosuppression or for any individual who is susceptible to measles, mumps or rubella. The Committee noted that the Priorix brand is approved for intramuscular (IM) administration and the MMR II brand is approved by Medsafe for subcutaneous (SC) administration, although MMR II is approved for IM administration in Australia and Europe.

9.7. The Committee noted that at its March 2019 meeting, it considered that either Priorix or MMR II brands of vaccine would be suitable as the funded brand in the Pharmaceutical Schedule.

9.8. The Committee agreed with its March 2019 recommendation and considered that either Priorix or MMR II were suitable for listing with Principal Supply Status in the Pharmaceutical Schedule, provided that MMR II could continue to be given IM administration, as this is current practise and there is no scientific reason to change. The Committee considered that IM administration is preferred within the wider sector as this is the current and familiar delivery mechanism for the MMR vaccine and some vaccinator types, such as pharmacists and outreach vaccinators, are not currently trained to administer vaccines by the SC route.

Meningococcal ACWY vaccine

9.9. The Committee noted that MenQuadfi and Menactra are the currently funded brands of meningococcal ACWY vaccine. Transition to funding only MenQuadfi is likely from April 2023. They are listed in the Pharmaceutical Schedule for previous cases and close contacts of meningococcal disease, people at higher risk of meningococcal disease through immunosuppression, and people who are 13-25 years of age living in specified close living situations.

9.10. The Committee noted that Menactra is approved for use in children from 9 months of age, MenQuadfi is approved for use in children from 12 months of age, and Nimenrix is approved for use from 6 weeks of age.

9.11. The Committee noted that at its May 2022 meeting, it considered that MenQuadfi would be a suitable replacment for Menactra, which is being discontinued, and that children under 12 months of age requiring meningococcal immunisation could receive Neisvac-C (funded meningococcal C vaccine).

9.12. The Committee noted that there have not been any reported cases of meningococcal C since 2020 and cases in 2021 and 2022 have been typed as groups B, W and Y. The Committee considered that as Nimenrix was approved for use from 6 weeks of age, it would be a more suitable vaccine in the Pharmaceutical Schedule, offering additional health benefit for children from 6 weeks to 11 months of age, compared with the currently funded MenQuadfi. The Committee noted that the supplier of MenQuadfi has indicated it intends to seek Medsafe approval for use in children from 6 weeks of age, likely in 2026.

9.13. The Committee considered that if Nimenrix was the funded brand in the Pharmaceutical Schedule, there would no longer be a need to have Neisvac-C listed as the health need for children under 12 months of age would be met, so Neisvac-C could be delisted.

9.14. The Committee considered that if Nimenrix was the funded brand, the meningococcal ACWY eligibilty criteria could be amended to align with the Nimenrix data sheet as shown below (additions in **bold**, deletions shown in ~~strikethrough~~):

Either:

A) Any of the following:
    1) 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
    2) One dose for close contacts of meningococcal cases of any group; or
    3) One dose for person who has previously had meningococcal disease of any group; or

4) A maximum of two doses for bone marrow transplant patients; or
5) A maximum of two doses for person pre- and post-immunosuppression*; or

B) Both:
1) Person is aged between 13 and 25 years, inclusive; and
2) 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, or prisons.

~~Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.~~
Note: infants from 6 weeks to less than 6 months of age require a 2+1 schedule, infants from 6 months to less than 12 months of age require a 1+1 schedule, individuals 12 months of age and over require one dose. Please refer to the Immunisation Handbook for the appropriate age-related schedule.
*Planned immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

Pneumococcal conjugate vaccine

9.15. The Committee noted it had recently considered pneumococcal conjugate vaccines at its August 2021, April 2022 and September 2022 meetings. The Committee noted that Pharmac widened access to PCV13 vaccine from 1 December 2022 and listed it in the Pharmaceutical Schedule with a 2+1 dosing schedule for children under 5 years of age.

9.16. The Committee noted and agreed with its September 2022 considerations that PCV15 and PCV13 vaccines likely provide comparable benefit at a population level and would therefore be considered interchangeable, based on the immunogenicity data reviewed at that meeting.

9.17. The Committee considered that ongoing pneumococcal surveillance was important and it would like to receive regular surveillance updates from ESR on the two additional serotypes covered by PCV15 vaccine (22F and 33F). The Committee requested that Pharmac ask the Public Health Agency to commission ESR to start reporting on all the serotypes covered by the PCV20 vaccine that is now available in some countries.

9.18. The Committee noted Pharmac is considering the funding of a 1 dose catch up programme for children under 5 years who have previously received PCV10 rather than PCV13 vaccine.

Rotavirus oral vaccine

9.19. The Committee noted that the rotavirus vaccine is currently listed in the Pharmaceutical Schedule with a two-dose schedule, given at age 6 weeks and 3 months milestone immunisation visits. The Committee noted that Rotarix is the currently funded brand, and Rota-Teq was the previously funded brand from 2014 to 2017, in a 2- and 3- dose schedule, respectively The Committee considered that the upper age limit for the last dose is 24 and 32 weeks for Rotarix and Rota-Teq, respectively because of the increased risk of intussusception if given later. The Committee noted that no cases of intussusception have been reported since Rotarix was funded in a 2 dose schedule.

9.20. The Committee considered that changing to Rota-Teq would add significantly to vaccinator workload for the third dose. It may also lower coverage because of the

upper age limit, and the increasing lateness of delivery of later doses. The Committee considered that the possible lower coverage of a 3-dose course would disproportionately affect Māori and Pacific children as there is lower on-time immunisation coverage for these children. The Committee considered that if Rota-Teq was funded, changes to the National Immunisation Schedule would be required to accommodate the third dose to be given at the 5 month visit. This would add to the workload on primary care to give an additional vaccine at the 5-month visit, in the context of the recent funding of meningococcal B vaccine, which added a third vaccine to be given at the 3, 5 and 12 month immunisation visits. The Committee considered that although either Rotarix or Rota-Teq would be appropriate for use in the New Zealand setting from a safety and efficacy perspective, a 2-dose schedule was strongly preferred from an immunisation programme implementation perspective.

9.21. The Committee considered that the additional vaccine stock required to support a three-dose schedule would put further pressure on vaccine fridge space in primary care. The Committee considered that fridge space was already under pressure due to influenza and COVID-19 programmes, and the recent funding of meningococcal B vaccine.

Varicella vaccine [chicken pox]

9.22. The Committee noted that Varivax is the currently funded brand of varicella vaccine, and that Varilrix was the previously funded brand from 2014 to 2017. The Committee noted that varicella vaccine is listed in the Pharmaceutical Schedule as a single dose for infants given at 15 months, and two doses for people at high risk from varicella. The Committee noted that Varivax is approved for use in individuals 12 months of age and older, and Varilrix is approved for use in individuals from 9 months of age.

9.23. The Committee considered that as varicella vaccination was not recommended for the national schedule in children younger than 12 months, either vaccine was suitable for inclusion in the Pharmaceutical Schedule for use in the National Immunisation Schedule. The Committee considered that the two vaccines are immunologically similar and usage would not be expected in children under 12 months of age.

Influenza vaccine

9.24. The Committee noted that Afluria Quad and Afluria Quad Junior quadrivalent inactivated vaccines (QIV) are the currently funded influenza vaccines on the Pharmaceutical Schedule, for people from 6 months of age and over.

9.25. The Committee noted that the RFP sought proposals for four different types of influenza vaccine: quadrivalent inactivated, both egg based and cell based (QIV), adjuvanted (aQIV), high dose (HD-QIV) and live attenuated influenza vaccines (LAIV). Suppliers were asked to submit proposals for principal supply status (PSS) and dual supply to cover the entire funded population. Proposals were also sought for widened access to groups that have already recommended for funding and are on the Options for Investment list, as follows:

- Children from 6 months up to 18 years of age
- All people 50 years of age and over
- Māori and Pacific peoples from 50 years of age and over
- Open listing (no restrictions)

9.26. The Committee noted that proposals were received for a range of different influenza vaccine technologies. The Committee considered that all vaccines included in bids were suitable for listing in the Pharmaceutical Schedule.

9.27. The Committee noted that one possible option regarding the supply of influenza vaccine could be to award PSS to the Viatris Influvac Tetra brand of QIV. The

Committee noted Influvac Tetra was previously the funded vaccine in the Pharmaceutical Schedule and also listed as an additional influenza vaccine when increased quantities have been required in some influenza seasons. The Committee noted that Influvac Tetra is approved for use in adults and children from 6 months of age.

9.28. The Committee considered that Influvac Tetra would be a suitable vaccine to list in the Pharmaceutical Schedule with PSS for the currently funded population and any of the groups for widened access that are on the Options for Investment list. The Committee considered that having a single funded vaccine approved for use from 6 months of age would simplify implementation of the influenza vaccine programme.

9.29. The Committee noted that one possible option regarding the supply of influenza vaccine could be to award dual supply to the Viatris Influvac Tetra brand of QIV and the Sanofi FluQuadri brand of QIV. The Committee noted that both Influvac Tetra and FluQuadri are approved for use in adults and children from 6 months of age. The Committee considered that in a dual supply scenario it would be necessary for both vaccines to be approved for use in people from the same age. The Committee considered that these two vaccines would be suitable for listing in the Pharmaceutical Schedule in a dual supply scenario.

Polio vaccine

9.30. The Committee noted that wild poliovirus types 2 and 3 have been eradicated, and type 1 is only endemic in the Afghanistan-Pakistan area. There have been increasing clusters of circulating vaccine-derived polio virus (cVDPV) since 2000 during the COVID-19 pandemic with the global polio eradication strategy compromised. Until recently, cases have been limited to developing countries with low immunisation coverage. In 2022, cVDPV cases were reported from UK, Israel and USA, with the virus also detected in wastewater in areas with no known cases. For type 2 polio virus, including cVDPV2, only about 1 in 2000 cases develop polio (in contrast to the overall polio risk of about 1 in 200); therefore, many more infections than cases would be expected. There is a theoretical risk that cVDPV could be imported to New Zealand; though cVDPV remains uncommon.

9.31. The Committee considered the currently funded IPOL polio vaccine would be suitable if a vaccination response was required following any imported vaccine-derived polio cases. The Committee considered that although the implementation of a mass campaign is considerably easier with an oral, rather than an injectable, vaccine; and that while OPV has the advantage of greater indirect protection by preventing transmission, there would be no need to use the Sabin monovalent oral polio vaccine type 2 recommended by the World Health Organization.

9.32. The Committee considered that while oral polio vaccine programmes have some advantages, the inactivated polio vaccine (IPOL) is preferred in the context of the New Zealand immunisation programme.