Immunisation Subcommittee of PTAC Meeting held 23 April 2013

(minutes for web publishing)

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Note:

 that this document is not necessarily a complete record of the Immunisation Subcommittee meeting; only the relevant portions of the minutes relating to Immunisation Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Respiratory Subcommittee 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.

These Subcommittee minutes were reviewed by PTAC at its meeting on 1 & 2 August 2013, the record of which will be available in October 2013.

Record of the

Immunisation Subcommittee of PTAC

Meeting

held on Tuesday 23 April 2013

Record of the Immunisation Subcommittee of PTAC meeting held on 23 April 2013

1 Clinically recommended action points

- 1.1 The Immunisation Subcommittee recommended:
 - 1.1.1 recommended amending the restrictions applying to the vaccines currently listed in the National Immunisation Schedule to reflect the number of doses an eligible patient could access.
 - 1.1.2 recommended that all vaccines discussed in the General review should include an allowance for revaccination of up to the entire number of vaccines for patients who have undergone HSCT, solid organ transplant or chemotherapy, with a high priority.
 - 1.1.3 Recommended that varicella vaccine be funded with a high priority for household contacts of patients who were immunocompromised or undergoing a treatment that would result in immune compromise
 - 1.1.4 Members requested that PHARMAC provide a further paper for HPV vaccine for males following chemotherapy including pharmacoeconomic modelling to the Subcommittee for consideration.
 - 1.1.5 Recommended funding either conjugated meningococcal C vaccine or a conjugated meningococcal A, C, Y, W135 vaccine with a high priority for patients post bone marrow transplant or chemotherapy or for patients post solid organ transplant or who are asplenic
 - 1.1.6 recommended that either conjugated group C meningococcal vaccine or meningococcal A, C, Y, W135 conjugated vaccine for close contacts of meningitis C cases be funded with a High priority
 - 1.1.7 recommended funding either conjugated group C meningococcal vaccine or meningococcal A, C, Y, W135 conjugated vaccine for community outbreaks of meningitis C with a high priority

2 General review of currently funded childhood vaccines

- 2.1 The Subcommittee noted that PHARMAC is responsible for determining eligibility for the funding of vaccines in New Zealand. Members noted that the National Immunisation Schedule (NIS) contained in the Pharmaceutical Schedule should reflect the number of doses of vaccination that are funded per product and the Immunisation Handbook should reflect the recommended timings for vaccination.
- 2.2 Members noted that being less specific with funded eligibility would not have a significant effect on usage but would allow accelerated vaccination or catch up dosing to occur. The Subcommittee noted that there that there was no need to capture all recommended timings of vaccines in the restrictions in the NIS but that rather the number of vaccines that a patient is eligible for did need to be explicitly noted on the NIS in the Pharmaceutical Schedule.
- 2.3 The Subcommittee noted the presence of an additional paper at this meeting considering the requirements for patients who were immunocompromised for any reason.

2.4 The Subcommittee recommended that the following note be applied to all childhood vaccines listed on the NIS:

Please refer to the Immunisation Handbook (or appropriate information site) for the appropriate schedule and for recommended timing of vaccinations and for catch up programme information.

In relation to diphtheria and tetanus vaccination

- 2.5 The Subcommittee noted that immunising individuals aged 7 years or older with the adult tetanus diphtheria (Td) or tetanus, diphtheria and pertussis (Tdap) vaccine was recommended. This was because of the risk of severe local reactions if the larger doses of diphtheria toxoid contained in the childhood vaccines (indicated by capital D) is administered to partially immune individuals aged 7 years or older.
- 2.6 The Subcommittee noted there was no registered Td or Tdap vaccine for children aged between 7 and 10 (the currently funded Boostrix vaccine is indicated from age 10 and older).
- 2.7 Members recommended that the currently funded diphtheria, tetanus and pertussis (Tdap) vaccine be funded for use for patients aged 7 years or older for up to four doses, to allow a catch-up programme for eligible patients who had not received the entire primary vaccination schedule.
- 2.8 Members considered that less than 5% of any annual patient cohort would require catch up using Tdap, as current coverage by 2 years of age was 95%. The Subcommittee considered the rate of unimmunised children requiring Tdap would be 1-2 % in a few years due to higher rates of primary immunisation.
- 2.9 Members considered that this widening of access may have an additional benefit in reducing pertussis if unimmunised patients had siblings under the age of 1 year, i.e. it may reduce transmission to babies and infants. The Subcommittee noted that there was substantial infectivity from siblings.
- 2.10 Members noted that there may be an underestimate of the morbidity associated with pertussis infection in older children. Members noted that even a mild case of pertussis can cause a prolonged cough lasting several weeks to months.
- 2.11 The Subcommittee recommended the following restrictions be applied to diphtheria, tetanus pertussis-containing vaccines (as DTaP-IPV or DTaP-IPV-HepB/Hib):

A course of up-to four vaccines is funded for children under the age of 7 years. Five doses will be funded for children requiring solid organ transplantation

Note: A course of up-to four vaccines is funded for catch up programmes for children (to the age of 7 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

2.12 The Subcommittee considered the following restrictions would be appropriate for Tdap:

A course of up-to four vaccines is funded for children from age 7 to 17 years inclusive

Note: A course of up-to four vaccines is funded for catch up programs for children (from age 7 to 17 years inclusive) to complete full primary immunisation. Tdap is not registered for patients aged less than 10 years.

- 2.13 The Subcommittee noted the diphtheria and tetanus vaccine Td was currently funded for patients aged 45 and 65. Members considered that the ages 45 and 65 was chosen for pragmatic reasons and were not aware of any scientific rationale for selecting this age range.
- 2.14 The Subcommittee considered that there may be a need to review the timing of Td in this patient group. Members also noted that it would be reasonable to consider Tdap in this age group and requested PHARMAC present a paper which included cost-effectiveness at the Subcommittee's next meeting.
- 2.15 The Subcommittee recommended the following restriction to allow appropriate access to Td for eligible patients:

Up to two doses is funded for adults aged between 45 and 65 years old.

One dose is funded for susceptible individuals.

2.16 The Subcommittee noted that, currently, general practice was bulk funded for wound care by ACC which included provision of tetanus vaccination for tetanus-prone wounds.

In relation to poliomyelitis vaccination

2.17 The Subcommittee noted the (inactivated poliovirus vaccine) IPV form of poliomyelitis vaccine is currently funded in the Pharmaceutical Schedule under the following restriction

A primary course of three doses for previously unvaccinated individuals

- 2.18 The Subcommittee considered that there were no problems with eligibility or access to polio vaccine in New Zealand.
- 2.19 The Subcommittee considered there was no role for the oral form of polio vaccine in New Zealand.
- 2.20 The Subcommittee noted that patients who require polio vaccination for travel purposes outside of the current eligibility criteria would be required to self-fund.

In relation to hepatitis B vaccination

2.21 The Subcommittee noted that the current restriction for hepatitis B vaccine was:

For household or sexual contacts of known hepatitis B carriers, or for children born to mothers who are hepatitis B surface antigen (HBsAg) positive.

2.22 The Subcommittee considered that for babies born to HBsAg positive mothers, hepatitis B vaccine as a course of four primary doses at birth, 6 weeks, 3 months and 5 months should be provided. If at 5 months the baby is HBsAg is negative and their anti-HBs level is ≤ 100 IU/I an additional two doses should be provided. Members noted that the doses at birth and any doses after age 5 months would be with monovalent hepatitis B vaccine, whereas the doses at 6 weeks, 3 months and 5 months would be as part of the hexavalent infant vaccine (DTaP-IPV-HepB/Hib).

- 2.23 The Subcommittee noted that there is international discussion about vaccinating all babies at birth in an attempt to eliminate hepatitis B.
- 2.24 The Subcommittee noted that teenagers who are tested and found to be nonimmune currently have to pay for additional vaccinations. Members further noted that younger children who do not seroconvert may need an additional four vaccinations. The Subcommittee considered it may be useful to fund universally up to four vaccinations, especially for patients exhibiting low serology.
- 2.25 The Subcommittee recommended that household and sexual contacts of Hepatitis B carriers should have a course of up to six vaccinations, an initial three vaccines plus an additional three depending on the serology response.
- 2.26 The Subcommittee noted that the funding details are different to the recommended timings in the immunisation programme. The Subcommittee noted that the current restrictions did not limit the numbers of doses and this was likely to be appropriate.
- 2.27 The Subcommittee recommended amending the restriction applying to hepatitis B vaccine as follows:

For household or sexual contacts of known hepatitis B carriers, or for children born to mothers who are hepatitis B surface antigen (HBsAg) positive, or for children up to the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination.

- In relation to Haemophilus influenzae type b (Hib) vaccination
- 2.28 The Subcommittee noted that the current restriction applying to *Haemophilus influenzae* type b (Hib) vaccine was:

For children aged 15 months, children aged 0-16 years with functional asplenia, or for patients pre- and post-splenectomy

- 2.29 The Subcommittee recommended that Hib should be available all children resident in New Zealand up to the age of 5 years, preferably administered when aged 15 months.
- 2.30 The Subcommittee recommend that the funding should be made available up to the age of 18 years in line with other vaccines, therefore the restrictions should be as follows:

1 dose funded for children up to the age of 5 years, or 1 dose for children aged children aged 0-18 years with functional asplenia, or for patients pre- and post-splenectomy, or post bone marrow transplant

In relation to tuberculosis vaccination

- 2.31 The Subcommittee discussed eligibility criteria and noted that the Ministry of Health determined eligibility of patients. Members noted that patients with tuberculosis (Tb) are eligible for funded health services in New Zealand. The Subcommittee noted that all eligible patients, in line with Ministry of Health eligibility criteria, should be funded up to the age of 18 years (i.e. aged 17 inclusive).
- 2.32 Members considered the current restriction to be appropriate as follows:

For infants at increased risk of tuberculosis (Tb). Increased risk is defined as:

 living in a house or family with a person with current or past history of Tb or
have one or more household members or carers who within the last 5 years lived in a country with a rate of Tb > or equal to 40 per 100,000 for 6 months or longer or
during their first 5 years will be living 3 months or longer in a country with a rate of Tb > or equal to 40 per 100,000
Note: a list of countries with high rates of Tb is available at www.moh.govt.nz/immunisation or www.bcgatlas.org/index.php

In relation to pneumococcal vaccine

2.33 The Subcommittee noted that the current restriction applying to pneumococcal conjugated vaccine (currently PCV10) was as follows:

For children aged 6 weeks, 3 months, and 5 months, and 15 months old

2.34 The Subcommittee considered that the following would be an appropriate funding restriction in the Pharmaceutical Schedule for pneumococcal conjugated vaccine (PCV10):

A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive

2.35 The Subcommittee noted that the current restriction applying to the pneumococcal conjugated 13 valent vaccine (PCV13) was as follows

For high risk children under the age of 5 years and those aged less than 16 years pre- or post-splenectomy or with functional asplenia.

2.36 The Subcommittee considered that the following would be an appropriate funding restriction in the Pharmaceutical Schedule for pneumococcal conjugated 13 valent vaccine (PCV13):

A primary course of four doses for previously unvaccinated high risk individuals up to the age of 59 months inclusive.

Up to two doses for those aged 2 years to 18 years pre- or post-splenectomy or with functional asplenia.

One dose is funded for high risk children who have previously received four doses of PCV10

2.37 The Subcommittee noted that the current restriction applying to the pneumococcal polysaccharide vaccine (23 valent) was as follows:

For patients pre- or post-splenectomy or children aged 0-16 years with functional asplenia.

2.38 The Subcommittee considered that the following would be an appropriate funding restriction in the Pharmaceutical Schedule for pneumococcal polysaccharide vaccine (23 valent):

Up to three doses for patients pre- or post-splenectomy or with functional asplenia.

Up to two doses are funded for high risk children

In relation to hexavalent vaccine; diphtheria, pertussis, polio, hepatitis B, Haemophillus influenza type B vaccine.

2.39 The Subcommittee noted that the current restriction applying to the infant hexavalent vaccine was as follows:

For children aged 6 weeks, 3 months, and 5 months old

2.40 The Subcommittee recommended that the following criteria be applied in the National Immunisation Schedule of the Pharmaceutical Schedule

A course of up to three vaccines is funded for children up to the age of 7 years inclusive.

3 Ministry of Health issue – tuberculosis (Tb) high risk countries

- 3.1 The Subcommittee noted that the Ministry of Health (MoH) has been reconsidering the definition of "high risk" countries for both Bacillus Calmette–Guérin (BCG) immunisation and immigration. The Subcommittee noted the currently-used tabulated schedule of all countries with a tuberculosis (Tb) annual incidence rate of ≥ 40 new cases per 100,000 population.
- 3.2 The Subcommittee noted that there may be a need to update the list of high risk countries. The Subcommittee discussed whether the ≥ 40 per 100,000 threshold might need to be adjusted for countries providing large numbers of immigrants to New Zealand. The Subcommittee noted that, apart from Tuvalu, there was not a high incidence of Tb recorded on that list for Pacific countries, but members could not exclude this perhaps reflecting low source population numbers and hence considerable statistical variability with incident events confined to one year's measurement. Members noted relatively high rates of Tb in New Zealand amongst Pacific peoples compared with many other ethnic groups
- 3.3 The Subcommittee recommended that there should be an exception list for the Pacific Islands even if their annual notification rates were below ≥ 40 per 100,000 (e.g. 39 per 100,000). The Subcommittee considered that the MoH should reconsider the notified incidence rate of Tb in Pacific countries and the appropriate threshold for these countries to be considered high risk.

4 Vaccines for patients pre and post immunosuppression

- 4.1 The Subcommittee noted that the primary immunisation vaccination schedule is fully funded for children under the age of 18 years and that while a number of catch-up programmes are clearly defined in the Immunisation Handbook, there are no programmes specifically recommended for children whose immunity may have been affected by health interventions.
- 4.2 The Subcommittee noted the draft paediatric oncology and asplenia vaccination guidelines 2013 provided by the National Children's Cancer Network. Members also noted that patients who have immunity affected by health interventions may require revaccination for certain vaccines or additional vaccines that were not currently funded for the general population.
- 4.3 The Subcommittee noted that the major immunocompromised patient groups being considered were bone marrow transplant (BMT) and solid organ transplant patients, patients post chemotherapy and those on high dose steroids or biologics. Members considered this should be on the recommendation of a paediatrician, haematologist, oncologist, rheumatologist or immunologist. Members considered

there would be approximately 300 patients per annum who would be eligible for funding in these groups.

- 4.4 The Subcommittee noted that patients who were previously vaccinated and had been immunosuppressed may require revaccination for certain vaccines. Members noted that the requirement for revaccination could be dependent on baseline titres for vaccine preventable illness.
- 4.5 The Subcommittee considered that where possible immunisations should be provided in general practice and recorded in the National Immunisation Register (NIR).
- 4.6 The Subcommittee considered that for children 3 to 6 months (as appropriate) following chemotherapy that a base titre for vaccine preventable diseases be obtained. The Subcommittee recommended that re-immunisation, or age appropriate immunisation, be funded for all vaccine preventable diseases where titres indicated no protection.
- 4.7 The Subcommittee considered that for children post solid organ transplant a base titre for vaccine preventable diseases be obtained. The Subcommittee recommended that re-immunisation, or age appropriate immunisation, be funded for all vaccine preventable diseases where titres indicated no protection.
- 4.8 The Subcommittee considered that those patients post hematopoietic stem cell transplant (HSCT) would require complete re-immunisation starting 12 months post-transplant, as they would be unlikely to have immunity to vaccine preventable diseases.
- 4.9 The Subcommittee noted that the requirement in patients post HSCT in catch-up programmes may have different requirements to previously unvaccinated children of the same age (non HSCT), due to the added risks to them from live vaccines.
- 4.10 The Subcommittee **recommended** that all vaccines discussed in the General review should include an allowance for revaccination of up to the entire number of vaccines for patients who have undergone HSCT, solid organ transplant or chemotherapy, with a high priority. The Subcommittee considered that a restriction broadly along the following lines for each vaccine would be appropriate:

An additional xx doses (as appropriate) are funded for (re-)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; pre- or post- solid organ transplant, renal dialysis and other severely immunosuppressive regimens

4.11 The Subcommittee considered that live vaccines should not be given to patients who were immunocompromised and this information should be made clear to vaccinators. Members considered that children who were immunocompromised were at high risk of contracting varicella and more likely to have severe, even fatal, varicella infection and secondary complications if infected. However, members noted that as varicella was a live vaccine, immunocompromised patients should not be given the vaccine. Therefore, the Subcommittee considered that, outside of universal vaccination, the next most effective prevention strategy would be to provide varicella vaccine cocooning. The Subcommittee noted that the varicella vaccine is currently not available on the National Immunisation Schedule. Members considered that providing varicella vaccination to household contacts of immunocompromised patients, or patients preparing to undergo a procedure leading to immune compromise, who had no history of varicella should be vaccinated.

4.12 The Subcommittee recommended that varicella vaccine be funded with a high priority with the following restriction:

Maximum of two doses for household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has:

- a) adult household contact a negative serology result for varicella
- b) child household contact no clinical history of varicella
- 4.13 The Subcommittee noted that no meningococcal vaccine (C or A, C, Y and W135) was currently on the childhood National Immunisation Schedule. Members considered that children who were immunocompromised or had undergone splenectomy were at higher risk of contracting meningococcal disease. Members noted that patients who had undergone splenectomy had a vastly increased risk of developing pneumococcal disease and considered that there would be a lower but still significantly increased risk of developing meningococcal disease for this patient group.
- 4.14 The Subcommittee noted that a conjugate meningococcal vaccine would be required as it is more immunogenic and develops lasting immunity. The polysaccharide vaccines risk hypo-responsiveness and are not immunogenic in patients aged less than 2 years.
- 4.15 Members noted that New Zealand still had a high incidence of meningococcal disease. Members noted that the major vaccine-preventable meningococcal group was the C group. Members considered that either conjugated meningococcal C vaccine or a conjugated meningococcal A, C, Y, W135 vaccine would be appropriate.
- 4.16 The Subcommittee recommended that either conjugated meningococcal C vaccine or a conjugated meningococcal A, C, Y, W135 vaccine be funded with a high priority with the following restriction:

Maximum of two doses for paediatric patients post bone marrow transplant or chemotherapy or

One dose every five years for patients post solid organ transplant or who are asplenic

- 4.17 The Subcommittee noted that human papilloma virus (HPV) vaccine was not currently on the childhood National Immunisation Schedule for males. Members considered that children who had reduced T cell immunity would likely be at greater risk of HPV infection. Members noted that solid organ transplant patients would also have a greater risk of HPV infection and complications in later life.
- 4.18 Members noted that patients who had undergone chemotherapy or HSCT had a higher general rate of cancer in later life. Members noted that 15-20% of survivors of childhood cancer would develop an adult cancer in later life.
- 4.19 The Subcommittee noted that for males that penile cancer and anogentical cancers comprised a small fraction of overall cancers experienced by the general population. Members considered that PHARMAC should undertake epidemiological modelling to help determine which specific patient groups would benefit most and cost-effectively from HPV vaccines for immunosuppressed boys. Members considered that females who had undergone chemotherapy or HSCT post HPV vaccinations should be considered for revaccination.

- 4.20 The Subcommittee considered there was insufficient information to make a recommendation for HPV vaccination at this time. Members requested that PHARMAC provide a further paper including pharmacoeconomic modelling to the Subcommittee for consideration.
- 4.21 The Subcommittee noted that hepatitis A vaccine was not currently on the childhood National Immunisation Schedule. Members considered hepatitis A vaccine was indicated for patients undergoing solid organ transplantation, particularly liver transplants. The Subcommittee noted that PHARMAC should seek further advice from DHBs as to the current use of hepatitis A vaccine in transplant patients.
- 4.22 Members noted that usage of hepatitis A for this indication would represent a small patient group and access in hospitals should not be restricted as part of PHARMACs Section H work, prior to a decision being made for community funding.
- 4.23 The Subcommittee noted its previous recommendation regarding eligibility to hepatitis B vaccine

For household or sexual contacts of known hepatitis B carriers, or for children born to mothers who are hepatitis B surface antigen (HBsAg) positive, or for children up to the age of 17 years inclusive who are considered not to have achieved a positive serology and require additional vaccination.

- 4.24 The Subcommittee considered that the requirement for positive serology would facilitate access to hepatitis B vaccination for patients post immunosuppression and that no further restrictions would be required.
- 4.25 The Subcommittee noted that there may be a requirement for additional presentations of hepatitis B vaccine, rDNA 10 mcg/ml, rDNA 20 mcg/ml and rDNA 40 mcg/ml. Members noted that the lower dose was required for patients under the age of 18 years, the 20 mcg/ml for those aged 18 years and older, and the 40 mcg/ml for patients undergoing liver or kidney transplant, or adult patients on renal dialysis
- 4.26 The Subcommittee considered that that there may be a requirement for influenza vaccine access to be considered for ring fencing of parents/household contacts of immunocompromised patients. Members asked that information be presented at its next meeting for consideration.

5 Timing of Measles Mumps and Rubella vaccination

- 5.1 The Subcommittee noted that currently doses of the measles, mumps and rubella vaccine (MMR) are recommended at 15 months and 4 years.
- 5.2 The Subcommittee considered that providing measles vaccination to patients under the age of 1 year did not provide long term immunity due to the potential presence of maternal antibodies in this patient cohort. Members considered that the key issue with MMR timing was to ensure early vaccination to prevent infection, but to also ensure that it was not provided too early (otherwise lowering long-term immunity).
- 5.3 The Subcommittee considered that approximately 90-95% of those vaccinated would develop immunity to measles from the first dose of MMR, with 90% of the non-responders developing immunity from a second dose.

- 5.4 The Subcommittee noted that as a result of recent measles outbreaks there had been changes to international recommendations to advance the timing of the measles vaccination forward to 12 months in order to increase coverage for the 12-15 month age group. The Subcommittee noted that the timing of MMR was 12-13 months in the UK and 12 months in Australia.
- 5.5 Members noted that New Zealand experienced an outbreak of measles in 2011 and that at that time 75% of the cases notified were in unvaccinated individuals.
- Members noted the De Serres et al study (Clin Infect Dis. 2012;55(3):403-5), 5.6 which described more than 750 cases of measles reported in 2011 in Quebec, Canada, where a routine 2-dose measles immunisation schedule (in which measles vaccine is given at 12 and 18 months of age) had been in effect since 1996. The effectiveness of this schedule was assessed during a high school outbreak. Measles cases were identified and followed up by active surveillance. Classical cases met the national surveillance definition; attenuated cases showed clinical signs and high measles-specific immunoglobulin G but did not fulfil all classical criteria. Immunisation status was ascertained from written records, and vaccine effectiveness (VE) was calculated as 1 - [(risk of measles in vaccinated individuals)/ (risk in unvaccinated individuals)] × 100%. Among 1306 students, 110 measles cases were identified; 98 being classical cases and 12 attenuated cases. The attack rates among unvaccinated students was 82% and fully vaccinated students was 4.8%, respectively. The VE among 2-dose recipients was 95.5% against classical and 94.2% against all (classical + attenuated) measles. Among 2dose recipients, attack rates with first immunisation at 12 and ≥15 months of age were 5.8% and 2.0%, respectively.
- 5.7 The Subcommittee noted that there was no data available as to long term vaccine effectiveness from the countries that have changed the timing from 15 months to 12 months.
- 5.8 The Subcommittee considered there would be no clinically significant issues for either mumps or rubella if the timing was changed to 12 months.
- 5.9 The Subcommittee considered the potential loss of vaccine efficacy from changing the timing of the MMR vaccine from 15 months to 12 months and the cost involved in this change at this time, and considered it would be inappropriate to recommend a change at this time.
- 5.10 The Subcommittee noted that if further evidence emerged suggesting that the vaccine was as efficacious when given at 12 months, or another vaccine that needed to be given at 12 months was introduced into the NIS, then this recommendation should be reviewed.

6 Meningococcal vaccines

6.1 Members noted New Zealand had a rate of meningococcal disease that is amongst the highest in the world. The Subcommittee noted that this was particularly the case in the late 1990s and early 2000s where there was an epidemic, mainly of B: P1.7-2.4. The Subcommittee noted that in 2011 there were 118 cases of meningococcal disease, 100 of which were typed; 37 cases were due to B:P1.7-2.4; 25 cases due to other group B infections; 27 cases due to C:P1.5-1,10-8; 5 cases due to other group C infection; with only small numbers of A, Y and W135 (total 6 cases across other groups).

- 6.2 Members noted that for the years 2007 2011, B:P1.7-2,4, infection was highest among those aged less than one year. Members note that infection from C:P1.5-1,10-8 had two peaks found in those age 1-4 and 15-19. The Subcommittee noted that Maori, Pasifika and those with the highest deprivation scores all have higher rates of disease.
- 6.3 Members noted that group B epidemics tend to have longer durations, whilst group C epidemics are shorter.
- 6.4 The Subcommittee noted that in New Zealand there are currently two quadrivalent polysaccharide meningococcal vaccines registered and that the Menomune A,C,Y,W-135 brand was funded under the following restriction:

For patients pre- and post-splenectomy or children aged 0-16 years with functional asplenia.

- 6.5 The Subcommittee recommended with high priority that the restriction should be amended to include children aged 0 to 18 years inclusive with functional asplenia.
- 6.6 The Subcommittee noted that there is evidence of conjugate vaccines proving better protection when compared with polysaccharide vaccines. Jackson et (PIDJ 2009; 28: 86-91) conducted an RCT comparing Menacra with Menomune in 524 participants age 11 -17 years. The Subcommittee noted that in this study that at 12 months, titers > =1:8 to meningococcal C were present in 77% Menactra participants, which was significantly higher than in Menomune participants (61%). The Subcommittee also noted that W135 titres were also significantly different in favour of Menactra (93% vs 68%).
- 6.7 Members noted that the conjugated meningococcal vaccines, for meningococcal C vaccine and meningococcal A, C, Y, W135 vaccines, would be preferred across all age groups, as conjugated meningococcal vaccine does not risk hyporesponsiveness and provides increased and more prolonged protection, and can be used in the under-2 year age group. The Subcommittee recommend that the polysaccharide vaccine should no longer be used.
- 6.8 The Subcommittee considered that the C and the A, C, Y, W135 conjugated meningococcal vaccines provided similar protection against meningococcal C. The Subcommittee recommended that the conjugated group C meningococcal vaccine would not require funding if the conjugated meningococcal A, C, Y, W135 vaccine was funded.
- 6.9 The Subcommittee noted that while meningococcal C vaccination was recommended for close contacts of meningitis C cases in the Ministry of Health Communicable Disease Control Manual 2012 and the Immunisation Handbook, it is not funded on the National Immunisation Schedule.
- 6.10 Members considered that for each case of meningitis C there would be approximately 10 close contacts requiring vaccination.
- 6.11 The Subcommittee **recommended** that either conjugated group C meningococcal vaccine or meningococcal A, C, Y, W135 conjugated vaccine for close contacts of meningitis C cases be funded with a High priority.
- 6.12 The Subcommittee noted that the Ministry of Health (MoH) Communicable Disease Control Manual 2012 defined a community outbreak of Neisseria meningitides invasive disease as being three or more confirmed cases of the same

strain (group and serotype) within a 3-month period and an age-specific incidence or specific community population incidence of approximately 10 per 100,000 where there is no other obvious link between the cases.

- 6.13 Members noted that where there was a community outbreak of Neisseria meningitidis C the current process was that the local medical officer of health determines necessary action in discussion with the Ministry of Health.
- 6.14 The Subcommittee noted that following the outbreak of meningitis C in Northland in 2011 the Immunisation Technical Forum (ITF) had been approached to provide advice to the MoH. The ITF advice was to vaccinate patients aged between 1 and 20 years but with a particular emphasis on high school students. Members noted that as in the case of Northland where there was a community outbreak (Mills. N Z Med J. 2011;124(1347):95-97) there was no central government funding of the vaccine.
- 6.15 The Subcommittee noted that it would be difficult to forecast these outbreaks and this may cause problems for the PHARMAC funding system.
- 6.16 The Subcommittee **recommended** funding either conjugated group C meningococcal vaccine or meningococcal A, C, Y, W135 conjugated vaccine for community outbreaks of meningitis C with a high priority.
- 6.17 The Subcommittee noted that there were other groups where a meningitis C vaccine was currently recommended but not funded, such as young adults in their first year of residence in hostel accommodation or military recruits.
- 6.18 The Subcommittee considered there was no evidence that targeting young adults in their first year of residence in hostel accommodation or military recruits was more effective than universal vaccine. Members noted that for young people in a hostel there was more likely to be close contact which would increase the risk of secondary transmission, but not the initial incidence.
- 6.19 The Subcommittee noted that other countries had introduced a universal meningitis C vaccine but that their incidences of disease were higher than in New Zealand. Members note that currently New Zealand had a rate of meningitis C infection of just less than 1.0 per 100,000 population.
- 6.20 The Subcommittee recommended that PHARMAC should prepare a paper for universal meningitis C vaccination including cost-utility analysis. Members considered this should include an initial vaccine at age 12 months and also include a catch-up programme. Members noted that the length of immunity should be varied in sensitivity analysis.

VA-MENGOC-BC – supplier advice request

6.21 The Subcommittee noted that the VA-MENGOC-BC was not appropriate to the predominant group B strain in New Zealand and members also noted that the efficacy of this component of the vaccine has been poor in the very young. The Subcommittee also noted that there was no definitive data on whether the C component of VA-MENGOC-BC has comparable efficacy to single component meningococcal C vaccines. The Subcommittee noted that there is no head-to-head clinical trial evidence currently available.

- 6.22 The Subcommittee considered that the strains that would be most beneficial to vaccinate against in the NZ population would be B:P1.7-2,4 and C:P1.5-1,10-8. The Subcommittee also noted that that it is extremely difficult to achieve satisfactory vaccine efficacy for B strain in those most at risk i.e. children aged less than 1 year.
- 6.23 The Subcommittee noted its previous comment that polysaccharides vaccines are less effective in those children aged less than 2 years and that conjugated vaccines should be considered, as they are more efficacious.

7 Outbreaks – local and national

- 7.1 The Subcommittee noted that PHARMAC is seeking to understand how it could best develop a system that would respond to outbreaks of vaccine-preventable illness in a timely manner, albeit from the perspective of vaccines funding.
- 7.2 The Subcommittee noted the Ministry of Health would be responsible for declaring pandemics that had a vaccine component, for example an influenza pandemic.
- 7.3 The Subcommittee noted that vaccination is not routinely part of outbreak control apart from in the case of Hepatitis A and meningococcal disease.
- 7.4 The Subcommittee considered that it would be beneficial to have access to funded vaccines for hepatitis A and meningitis C for close contacts as per the MoH Communicable Disease Control Manual 2012.
- 7.5 Members noted that vaccination for large groups as a result of a meningitis C outbreak was recommended and this had significant cost implications, as well as access to vaccination.
- 7.6 Members considered that local medical officers of health would usually identify an outbreak and would be involved in the response. The Subcommittee considered that it may be appropriate to have a funding restriction requiring the Medical Officer of Health to discuss the outbreak with the Director of Public Health before initiating a vaccine response.
- 7.7 The Subcommittee considered that PHARMAC should investigate how it could be involved with funding and present a paper to the Subcommittee at its next meeting. The Subcommittee noted that the paper should focus on hepatitis A and meningitis C vaccination in an outbreak setting.
- 7.8 Members considered that the Institute of Environmental Science and Research (ESR) reports were not sufficiently timely and recommended that if full annual reports for preceding year were not available then the most recent quarterly reports should be provided for consideration.