PHARMAC
Pharmaceutical Management Agency

17 December 2013

Changes to the National Immunisation Schedule

PHARMAC is pleased to announce decisions related to the National Immunisation Schedule (NIS) that will take effect from 1 July 2014. This was the subject of a consultation letter dated 6 November 2013, which can be found at the following link: http://www.pharmac.health.nz/news/item/national-immunisation-schedule.

The decisions mean that from 1 July 2014:

The following new vaccines will be listed in the NIS:

- rotavirus vaccine (for all eligible patients);
- varicella vaccine (for patients at high risk from infection);
- hepatitis A vaccine (for eligible patients);
- a higher strength hepatitis B vaccine for the vaccination of dialysis patients and patients who have had a liver or kidney transplant; and
- a monovalent conjugated meningococcal C vaccine.

Changes to funding for the following vaccines currently listed in the NIS:

- The eligibility age for funding for HPV (Gardasil) vaccine for females will be changed to 'up to 18 years'.
- Revaccination of children following significant immunosuppression (for example as a result of chemotherapy) will be funded for all vaccines.

Other changes:

- The 10 valent pneumococcal vaccine (Synflorix) vaccine will be replaced with the 13 valent (Prevenar 13) pneumococcal vaccine.
- The currently listed polysaccharide meningococcal A, C, Y and W-135 (Menomune) vaccine will be replaced with the conjugate meningococcal A, C, Y and W-135 (Menactra) vaccine.

Responses to consultation

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 4pm 20 November 2013 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal. Themes in the responses, and PHARMAC commentary on those themes, are included at the end of this notification.

A number of responders requested that PHARMAC consider widening access to the proposed vaccines to include new patient populations (i.e. immunocompromised adults) or wider access than that proposed. PHARMAC will consider these requests as new funding applications. We will seek advice as to the clinical benefits of widening access to the requested new populations and may be in contact with responders for further clarification, clinical evidence or comment. For the avoidance of doubt, PHARMAC is able to make further changes to access restrictions outside of the current three year contracting cycle for the NIS.

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Details of the decision

Rotavirus vaccine

From 1 July 2014 RotaTeq will be listed in the National Immunisation Schedule.

RotaTeq will be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Rotavirus live reassortant oral vaccine	Oral susp G1, G2, G3, G4, P1(8)11.5 million CCID50 units/2 mL, tube	RotaTeq	10	$0.00

RotaTeq will be listed in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) from 1 July 2014 with the following indication restrictions:

> Maximum of three doses for patients meeting the following:
> 1. first dose to be administered in infants aged under 15 weeks of age; and
> 2. no vaccination being administered to children aged 8 months or over.

RotaTeq will have sole supply status in both the hospital and community settings for rotavirus vaccine from 1 July 2014 until 30 June 2017.

Varicella zoster vaccine

From 1 July 2014 Varilrix will be listed in the National Immunisation Schedule.

Varilrix will be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Varicella-zoster live attenuated vaccine	Injection OKA strain 2000 PFU vial with diluent	Varilrix	1	$0.00

Varilrix will be listed in Section I (National Immunisation Schedule) from 1 July 2014 with the following indication restrictions:

> Maximum of two doses for any of the following:
> 1. For non-immune patients:
> 1.1 with chronic liver disease who may in future be candidates for transplantation; or
> 1.2 with deteriorating renal function before transplantation; or
> 1.3 prior to solid organ transplant; or
> 1.4 prior to any elective immunosuppression*.
> 2. For patients at least 2 years after bone marrow transplantation, on advice of their specialist.
> 3. For patients at least 6 months after completion of chemotherapy, on advice of their specialist.

4. For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist.
5. For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has:
   5.1 adult household contact - a negative serology result for varicella; or
   5.2 child household contact - no clinical history of varicella or negative varicella serology.

* immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days

Varilrix will be listed as the varicella-zoster vaccine in Section H (the Hospital Medicines List) from 1 July 2014 with the current indication restrictions as follows:

Maximum of two doses for any of the following:

1. For non-immune patients:
   1.1 with chronic liver disease who may in future be candidates for transplantation; or
   1.2 with deteriorating renal function before transplantation; or
   1.3 prior to solid organ transplant; or
   1.4 prior to any elective immunosuppression*; or
   1.5 for post exposure prophylaxis who are immune competent inpatients.
2. For patients at least 2 years after bone marrow transplantation, on advice of their specialist.
3. For patients at least 6 months after completion of chemotherapy, on advice of their specialist.
4. For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist.
5. For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has:
   5.1 adult household contact - a negative serology result for varicella; or
   5.2 child household contact - no clinical history of varicella or negative varicella serology.

* immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days

Varilrix will have sole supply status in both the hospital and community settings for varicella vaccine from 1 July 2014 until 30 June 2017.

For the avoidance of doubt, the 1350 PFU vial with diluent presentation of varicella zoster vaccine will be delisted from Section H from 1 July 2013.

Pneumococcal conjugate vaccine

From 1 July 2014 Prevenar 13 will be listed in the National Immunisation Schedule. From 1 October 2014 Prevenar 13 will be the only listed pneumococcal conjugate vaccine for the National Immunisation Schedule.

Prevenar 13 will be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Pneumococcal (PVC13) conjugate vaccine	Inj 30.8 mcg in 0.5 ml syringe	Prevenar 13	1	0.00
Pneumococcal (PVC13) conjugate vaccine	Inj 30.8 mcg in 0.5 ml syringe	Prevenar 13	10	0.00

From 1 July 2014 the current restrictions applying to Pneumococcal 13-valent protein conjugate vaccine (PCV13) in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) will be deleted and replaced with the following indication restrictions:

> Any of the following:
> 1. A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive; or
> 2. Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV10; or
> 3. One dose is funded for high risk children who have previously received four doses of PCV10; or
> 4. Up to an additional four doses (as appropriate) are funded for (re-)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis and other severely immunosuppressive regimens up to the age of 18; or
> 5. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.
>
> Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes

Synflorix will remain listed under its current criteria until 30 September 2014 as part of a transition period to allow for remaining stock to be used by vaccinators. Synflorix will be delisted from 1 October 2014.

Prevenar 13 will have sole supply status in both the community and hospital settings for pneumococcal conjugate vaccine from 1 October 2014 until 30 June 2017

Meningococcal (Groups A, C, Y and W-135) polysaccharide diphtheria toxoid conjugate vaccine

From 1 July 2014 Menactra will be listed in the National Immunisation Schedule.

Menactra will be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Meningococcal (Groups A,C,Y and W-135) congugate vaccine	Injection 4 mcg of each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 mL vial	Menactra	1	$0.00

The meningococcal polysaccharide vaccine (under the brand name Menomune) of meningococcal A, C, Y and W-135 vaccine injection will be delisted from Section I of the Pharmaceutical Schedule from 1 October 2014.

From 1 July 2014 Menactra will be listed as the meningococcal (groups A, C, Y and W-135) conjugate vaccine in Section I (National Immunisation Schedule) with the following indication restrictions:

Any of the following:
1. One dose for patients pre- and post-splenectomy; or
2. One dose every five years for patients with functional asplenia or post solid organ transplant; or
3. One dose for close contacts of meningococcal cases; or
4. A maximum of two doses for bone marrow transplant patients; or
5. A maximum of two doses for patients following immunosuppression.

From 1 July 2014 Menactra will be listed as the meningococcal (groups A, C, Y and W-135) conjugate vaccine in Section H (the Hospital Medicines List) under the current restrictions as follows:

Any of the following:
1. For patients pre- and post-splenectomy; or
2. For children aged 0-18 years with functional asplenia; or
3. For organisation and community based outbreaks; or
4. For use in transplant patients; or
5. For use following immunosuppression.

Menactra will have sole supply status in both the community and hospital settings for Meningococcal (Groups A, C, Y and W-135) conjugate vaccine from 1 July 2014 until 30 June 2017.

Meningococcal C conjugate vaccine

From 1 July 2014 Neisvac-C will be listed in the National Immunisation Schedule.

Neisvac-C will be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Meningococcal C conjugate vaccine	Inj 10 mcg in 0.5 ml syringe	Neisvac-C	1	0.00
Meningococcal C conjugate vaccine	Inj 10 mcg in 0.5 ml syringe	Neisvac-C	10	0.00

Neisvac-C will be listed Section I (National Immunisation Schedule) from 1 July 2014 with the following indication restrictions:

Any of the following:
1. One dose for patients pre- and post-splenectomy; or
2. One dose every five years for patients with functional asplenia or post solid organ transplant; or
3. One dose for close contacts of meningococcal cases; or
4. A maximum of two doses for bone marrow transplant patients; or

5. A maximum of two doses for patients following immunosuppression.

Neisvac-C will be listed in Section H (the Hospital Medicines List) as the conjugate meningococcal C vaccine from 1 July 2014 under the current indication restrictions as follows:

Any of the following:
1. For patients pre- and post-splenectomy; or
2. For children aged 0-18 years with functional asplenia; or
3. For organisation and community based outbreaks; or
4. For use in transplant patients; or
5. For use following immunosuppression.

Neisvac-C will have sole supply status in both the hospital and community settings for conjugated meningococcal C vaccine from 1 July 2014 until 30 June 2017.

Hepatitis A vaccine

From 1 July 2014 Havrix and Havrix Junior will be listed in the National Immunisation Schedule.

Havrix and Havrix Junior will be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Hepatitis A vaccine	Inj 1440 ELISA units in 1 ml syringe	Havrix	1	$0.00
Hepatitis A vaccine	Inj 720 ELISA units in 0.5 ml syringe	Havrix Junior	1	$0.00

Havrix and Havrix Junior will be listed in Section H (the Hospital Medicines List) and remain listed in Section I (National Immunisation Schedule) from 1 July 2014 with the following indication restrictions:

Funded for patients meeting any of the following criteria:
1. Two vaccinations for use in transplant patients; or
2. Two vaccinations for use in children with chronic liver disease; or
3. One dose of vaccine for close contacts of known hepatitis A cases; or
4. One dose for any of the following on the recommendation of a local medical officer of health
   4.1. Children, aged 1–4 years inclusive who reside in Ashburton district; or
   4.2. Children, aged 1–9 years inclusive, residing in Ashburton; or
   4.3. Children, aged 1–9 years inclusive, who attend a preschool or school in Ashburton; or
   4.4. Children, aged older than 9 years, who attend a school with children aged 9 years old or less, in Ashburton funded for children in Ashburton.

Havrix and Havrix Junior will have sole supply status in both the community and hospital settings for hepatitis A vaccine from 1 July 2014 until 30 June 2017.

Diphtheria, tetanus and acellular pertussis vaccine

From 1 July 2014 Boostrix will remain listed on the National Immunisation Schedule.

Boostrix will continue to be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Diphtheria, tetanus and pertussis vaccine	Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagluttinin and 2.5 mcg pertactin in 0.5 ml syringe	Boostrix	1	$0.00
Diphtheria, tetanus and pertussis vaccine	Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagluttinin and 2.5 mcg pertactin in 0.5 ml syringe	Boostrix	10	$0.00

From 1 July 2014 the current restrictions applying to diphtheria, tetanus and pertussis vaccine Tdap in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) will be deleted and replaced with the following indication restrictions:

> Funded for any of the following
>
> 1. A single vaccine for pregnant woman between gestational weeks 28 and 38 during epidemics.
> 2. A course of up-to four vaccines is funded for children from age 7 to 17 years inclusive to complete full primary immunisation.
> 3. A course of up-to four vaccines is funded for children from age 7 to 17 years inclusive for re-immunisation following immunosuppression
>
> Note: Tdap is not registered for patients aged less than 10 years.

Boostrix will have sole supply status in both the community and hospital settings for Tdap from 1 July 2014 until 30 June 2017.

Diphtheria, tetanus, acellular pertussis and inactivated polio vaccine

From 1 July 2014 Infanrix IPV will remain listed on the National Immunisation Schedule.

Infanrix IPV will continue to be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Diphtheria, tetanus, pertussis and inactivated polio vaccine	Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagluttinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5 ml syringe	Infanrix IPV	10	$0.00

From 1 July 2014 the current restrictions applying to DTaP-IPV in Section H (the Hospital Medicines List) and in Section I (National Immunisation Schedule) will continue to apply as follows:

> Funded for any of the following
>
> 1. A single dose for children up to the age of 7 who have completed primary immunisation; or
> 2. 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.
> 3. An additional four 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. Five doses will be funded for children requiring solid organ transplantation.
>
> Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Infanrix IPV will have sole supply status in both the community and hospital settings for DTaP-IPV from 1 July 2014 until 30 June 2017.

Hepatitis B vaccine

From 1 July 2014 three strengths of HBvaxPRO will be listed on the National Immunisation Schedule.

HBvaxPRO will continue to be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Hepatitis B recombinant vaccine	Inj 5 mcg per 0.5 ml vial	HBvaxPRO	1	$0.00

Hepatitis B recombinant vaccine	Inj 10 mcg per 1 ml vial	HBvaxPRO	1	$0.00
Hepatitis B recombinant vaccine	Inj 40 mcg per 1 ml vial	HBvaxPRO	1	$0.00

From 1 July 2014 the current restriction applying to hepatitis B vaccine in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) will be deleted and replaced with the following indication restrictions for the HBvaxPRO 5 mcg per 0.5 ml and 10 mcg per 1 ml presentations:

> Funded for any of the following criteria:
>
> 1. for household or sexual contacts of known hepatitis B carriers; or
> 2. for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or
> 3. for children up to the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination; or
> 4. for HIV positive patients; or
> 5. for hepatitis C positive patients; or
> 6. for patients following immunosuppression; or
> 7. for transplant patients.

HBvaxPRO 40 mcg per 1 ml vaccine will be listed in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) from 1 July 2014 with the following indication restrictions:

> Funded for any of the following criteria:
>
> 1. for dialysis patients; or
> 2. for liver or kidney transplant patient.

HBvaxPRO will have sole supply status in both the community and hospital settings for hepatitis B vaccine from 1 July 2014 until 30 June 2017.

Inactivated poliomyelitis vaccine

From 1 July 2014 IPOL will remain listed on the National Immunisation Schedule.

IPOL will continue to be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Inactivated poliomyelitis vaccine	Inj 80D antigen units in 0.5 ml syringe	IPOL	1	$0.00

From 1 July 2014 the current restriction applying to inactivated poliomyelitis vaccine in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) will be deleted and replaced with the following indication restrictions:

> Up to three doses for patients meeting either of the following:
>
> 1. For previously unvaccinated individuals; or
> 2. For revaccination following immunosuppression.

IPOL will have sole supply status in both the community and hospital settings for inactivated poliomyelitis vaccine from 1 July 2014 until 30 June 2017.

Human papilloma virus vaccine

From 1 July 2014 Gardasil will remain listed on the National Immunisation Schedule.

Gardasil will continue to be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Human papilloma virus (6,11,16 and 18)	Inj 120 mcg in 0.5 ml syringe	Gardasil	10	$0.00

From 1 July 2014 the current restriction applying to HPV vaccines in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) will be deleted and replaced with the following indication restrictions:

> Maximum of three doses for patient meeting any of the following criteria:
>
> 1. Women aged under 18 years old; or
> 2. Patients aged under 25 years old with confirmed HIV infection; or
> 3. For use in transplant patients.

Girls born in the birth cohorts 1994, 1995, 1996 and 1997 will have until 31 December 2014 to commence the HPV programme and will be funded to complete the programme if they commenced it before 31 December 2014.

Gardasil will have sole supply status in both the community and hospital settings for HPV vaccine from 1 July 2014 until 30 June 2017.

Adult diphtheria and tetanus vaccine

From 1 July 2014 ADT Booster will remain listed on the National Immunisation Schedule.

ADT Booster will continue to be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Adult diphtheria and tetanus	Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml	ADT Booster	5	$0.00

From 1 July 2014 the current restriction applying to Td vaccines in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) will be deleted and replaced with the following indication restrictions:

Any of the following:

1. For vaccination of patients aged 45 and 65 years old; or
2. For vaccination of previously unimmunised patients; or
3. For revaccination following immunosuppression; or
4. For revaccination for patients with tetanus-prone wounds; or
5. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

ADT Booster will have sole supply status in both the community and hospital settings for Td vaccine from 1 July 2014 until 30 June 2017.

Measles, mumps and rubella vaccine

From 1 July 2014 M-M-R-II will remain listed on the National Immunisation Schedule.

M-M-R-II will continue to be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Measles, mumps and rubella vaccine	Inj 1000 TCID50 measles, 12500 TCID50 mumps and 1000 TCID50 rubella vial with diluent 0.5 ml vial	M-M-R-II	10	$0.00

From 1 July 2014 the current restriction applying to MMR vaccines in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) will be deleted and replaced with the following indication restrictions:

A maximum of two doses for any patient meeting the following criteria:

1 For primary vaccination in children; or

2 For revaccination following immunosuppression; or

3 For any individual susceptible to measles, mumps or rubella

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

M-M-R-II will have sole supply status in both the community and hospital settings for MMR from 1 July 2014 until 30 June 2017.

Pneumococcal polysaccharide vaccine

From 1 July 2014 Pneumovax 23 will remain listed as the pneumococcal polyvalent polysaccharide vaccine for the National Immunisation Schedule.

Pneumovax 23 will continue to be centrally purchased by PHARMAC's nominated agent (currently Environmental Science and Research) and distributed directly to vaccinators at no cost.

Chemical	Presentation	Brand	Pack size	Subsidy
Pneumococcal (PPV23) polysaccharide vaccine	Inj 575 mcg in 0.5 ml vial	Pneumovax 23	1	$0.00

From 1 July 2014 the current restriction applying to pneumococcal polyvalent vaccine in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) will be deleted and replaced with the following indication restrictions:

Either of the following:

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

2 Up to two doses are funded for high risk children to the age of 18.

Pneumovax 23 will have sole supply status in both the hospital and community settings for pneumococcal polysaccharide vaccine from 1 July 2014 until 30 June 2017.

Feedback received

As noted earlier, we appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 20 November 2013 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	PHARMAC staff response
Rotavirus vaccine	
There should be information on the risks of intussuception and some surveillance of this. Asked whether rotavirus will be made notifiable or have sentinel site monitoring of rotavirus. Considered it important to monitor for benefit of vaccine.	Noted. PHARMAC will discuss with Ministry of Health (MoH) requirements for information and surveillance.

Theme	PHARMAC staff response
PHARMAC and the Ministry of Health (MoH) must collaborate to ensure timely effective implementation.	Noted. Programme implementation to achieve set targets remains the responsibility of the MoH; PHARMAC staff will pass the feedback on to the MoH Immunisation team.
Varicella zoster vaccine	
Requested universal vaccination. Considered risks of zoster are small if high rate of vaccination can be achieved. Further noted that there is now a zoster vaccine which could become part of an adult schedule.	Noted. PTAC considered the advice of the Immunisation Subcommittee regarding universal vaccination and the potential risks of an increase in zoster as a result of this. PHARMAC will continue to evaluate the potential for universal varicella vaccination as information develops; substantive new information contained in consultation responses will be provided to PTAC for consideration.
Requested that criteria for household contacts be extended (beyond paediatric patients) to include adult patients who are immunocompromised, i.e. if an adult is undergoing immune suppressive therapy then children in that household who are not immune should be vaccinated	PHARMAC has not assessed the budget impact of funding vaccine for all immunosuppressed adults. We will seek advice from the Immunisation Subcommittee as to the health needs of this patient group.
Requested that eligibility criteria include patients with metabolic diseases.	PHARMAC will seek the advice of the Immunisation Subcommittee as to the health needs of this patient group.
Recommended a number of changes, including patients with chronic kidney disease who may be candidates for transplant, and widening criteria for household contacts from contacts of paediatric immunocompromised patients to contacts of any age.	These changes will be considered as new funding applications.
Pneumococcal conjugate 13 valent vaccine	
Considered that those at greatest risk of pneumococcal disease, eg pre- or post- splenectomy patients, should receive this vaccine at any age.	PHARMAC has not assessed the budget impact of funding vaccine for all immunosuppressed adults. We will seek advice from the Immunisation Subcommittee as to the health needs of this patient group.
Considered that the PCV 10 vaccine conjugated to a non-typable *Haemophillus influenza type B* would provide a greater benefit in reducing acute otitis media compared with the proposed PCV13.	PHARMAC considered the potential impact of PCV10 on acute otitis media (AOM) as part of the evaluation of the pneumococcal conjugate vaccines, and the PCV13 proposal was considered more cost effective.
Have instituted a surveillance program and a study of the microbiology of otitis media in New Zealand to see if there is a substantial difference with Synflorix's activity against *Haemophilus* species. The study won't be able to follow this up because it is impossible to delineate a difference between the two vaccines when they have been changed at such short intervals.	Noted.
Meningococcal conjugate C vaccine	
Sought clarification on how PHARMAC would consider funding community outbreaks.	As per the consultation document, PHARMAC intends to develop a process for community outbreaks.
Meningococcal vaccines should be considered for the following groups: • complement deficiency • universal vaccination • people entering communal living (army, hostels) Recommended vaccinating HIV infected adolescents, patients with chronic kidney disease, and infants under one year age with any of the at-risk indications.	The Immunisation Subcommittee has requested a cost utility analysis be undertaken on universal vaccination in order to give advice on this potential change.
Recommended PHARMAC consider a combined meningococcal with HiB vaccine.	PHARMAC is not aware of a registered combination meningococcal with HiB vaccine. PHARMAC would consider any funding application in accordance with its usual processes.

Diphtheria, tetanus, acellular pertussis and inactivated polio vaccine	
Recommended changing the upper age limit for catch-ups from 7 years to 10.	Changes have been made to the criteria.
Hepatitis B vaccine	
Considered that patients with chronic kidney disease stage 4 (eGFR 15-30mls) are at high risk of progressing to end stage renal disease and should be proactively vaccinated.	PHARMAC intends to consider this as a new application for funding.
Hepatitis A vaccine	
Considered that the indications should include adults with chronic liver disease, not just children.	PHARMAC intends to consider this as an application for funding. We will seek the advice of Immunisation Subcommittee to inform the assessment of cost effectiveness.
Recommended the addition of two doses for HIV infected individuals and two doses for patients with chronic Hepatitis B.	PHARMAC intends to consider this as an application for funding. We will seek the advice of Immunisation Subcommittee to inform the assessment of cost effectiveness.
Adult diphtheria, tetanus, acellular pertussis vaccine (TDaP)	
Supported the continuing programme of vaccination of pregnant women outside of epidemics.	As noted in the consultation document, PHARMAC intends to seek advice in 2014 from the Immunisation Subcommittee, in order to review of the use of TDaP vaccine in pregnancy during epidemics.
Supported the proposal to widen access to children aged 7-17 for primary vaccination. Noted that it is not registered for children < 10 years.	The funding restriction includes a note that it is an unregistered indication.
Consider that TDaP should replace the tetanus diphtheria vaccine at age 45 and 65 on the schedule and that TDaP should also be used when patients require a diphtheria/tetanus booster.	PHARMAC intends to consider this as an application for funding. We will present the information provided to the Immunisation Subcommittee to inform the assessment of cost effectiveness.
Consider TDaP should be funded for health care workers and other high risk occupations (contact with children).	PHARMAC considers that occupational health vaccinations should be provided by the employer.
Adult diphtheria and tetanus vaccine	
Recommended the restriction referring to the revaccination of patients with tetanus prone wounds should include reference to the patients' last vaccination being 5 or more years ago.	Noted. This however should be part of routine good clinical practice, and the Pharmaceutical Schedule does not provide explicit therapeutic detail.
Human papillomavirus (HPV) vaccine	
Considered it would be difficult to target funding to the MSM population, especially prior to exposure to HPV.	Noted.
Requested universal funding of males.	PHARMAC will undertake further analysis of this.
If universal male vaccination is uneconomic, then seek funding for young males self-identifying as males who have sex with males.	The PTAC recommended HPV vaccine for males aged between 9 and 26 years who self-identify as having sex with other males be listed with high priority. PHARMAC will be undertaking further analysis of this.
Request the 20 year age limit be retained, as parents may block young women's access to HPV immunisations when younger	The MoH recommended the change to 18 years and will be updating its material.
Consider the HIV recommendation should be for both males and females. Question the 25 year old age limit.	PHARMAC has amended the restriction to include females with HIV. The proposed restriction for use in males reflects the registered indication for use of Gardasil in males i.e. up to the age of 26 years.
Recommended extending access to gay and bisexual men, to all HIV positive individuals. It would be more equitable to include female patients under the age of 45 with confirmed HIV infections.	PHARMAC has amended the restriction to include females with HIV up to the age of 25 years. Extending access to include women aged 26 to 44 can be considered as a new application for funding.

Strongly recommend that PHARMAC adopts the PTAC recommendation for vaccination of men who have sex with men but do not have HIV. Note that gay and bisexual men have a rate of HPV related illness 20 times higher than the general population. Contend that not offering HPV vaccination for this group would be discriminatory. Recommend that PHARMAC should engage with experts in these fields to inform decision making.	PHARMAC will be undertaking further analysis of this issue.
Note that the recommendations differ from those in MoH's consumer information.	The MoH will be updating its materials.
General feedback	
Note the lack of compensation for the time-consuming process of obtaining parental consents, and the growing workload associated with recalls and managing the national immunisation programme.	PHARMAC will pass on this information to the MoH, which is responsible for the national immunisation programme.
Requests consistency in the wording for the immunosuppression criteria.	The wording has been aligned.
Highlights the importance of decisions around vaccines being based on the epidemiology of disease in the community, with vaccine purchasing decisions following decisions around the national schedule.	PHARMAC considers the advice and recommendations made by PTAC and its Immunisation Subcommittee when deciding vaccine funding and access criteria. PHARMAC is responsible for making decisions about which vaccines will be funded in New Zealand – a decision that was made by the Government in 2012. Decoupling the requirements for establishing the contents of the NIS from the procurement activity would significantly undermine the ability for PHARMAC to obtain the best value from various proposals put forward. This would either reduce the ability for PHARMAC to extend access to vaccines, or have impacts on the availability of medicines or other health interventions, through forgoing trade-offs elsewhere.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.