CONSULTATION

PHARMAC
Pharmaceutical Management Agency

6 November 2013

Proposal to amend listings in the National Immunisation Schedule

PHARMAC is seeking feedback on proposals relating to provisional agreements with a number of suppliers for the supply of vaccines for the New Zealand National Immunisation Schedule.

Among the proposed changes are the following:

New Listings:

The proposals would see the following new vaccines listed on the National Immunisation Schedule from 1 July 2014:

- 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.

Access Changes from 1 July 2014:

- The eligibility age for funding for HPV (Gardasil) vaccine for females would be changed to 'up to 18 years'.

- Funded access to vaccines would be amended to allow revaccination of children following significant immunosuppression (for example as a result of chemotherapy)

Other Changes:

- The 10 valent pneumococcal vaccine (Synflorix) vaccine would be replaced with the 13 valent (Prevenar 13) vaccine.

- The currently listed polysaccharide meningococcal A, C, Y and W-135 (Menomune) would be replaced with the conjugate meningococcal A, C, Y and W-135 (Menactra)

Provisional agreements for listing of the vaccines have been reached with the following suppliers:

- bioCSl
  - adult diphtheria and tetanus vaccine (ADT Booster); and
  - human papillomavirus (6, 11, 16 and 18) vaccine (Gardasil)

- GlaxoSmithKline
  - diphtheria, tetanus and acellular pertussis vaccine (Boostrix); and
  - diphtheria, tetanus, acellular pertussis and inactivated polio vaccine (Infanrix IPV); and

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        - varicella-zoster vaccine (Varilrix); and
        - hepatitis A vaccine (Havrix and Havrix Junior)

    - Merck Sharp and Dohme
        - measles, mumps, and rubella virus vaccine live (M-M-R II); and
        - hepatitis B recombinant vaccine (HBvaxPRO); and
        - pneumococcal polyvalent vaccine (Pneumovax 23); and
        - rotavirus vaccine (RotaTeq)

    - Sanofi Aventis
        - inactivated Poliomyelitis Vaccine (IPOL); and
        - meningococcal A, C , Y and W135 vaccine (Menactra)

    - Pfizer
        - Pneumococcal conjugate 13 valent (PCV13) vaccine (Prevenar 13)

    - Baxter Healthcare
        - Meningococcal C conjugate vaccine (Neisvac-C)

- All contracted vaccines would have Sole Subsidised Supply and Hospital Supply status, making them the only vaccines listed in both the Community and Hospitals.

At this time PHARMAC has not entered into provisional agreements for the *Haemophilus influenzae type B* vaccine, Bacillus Calmette-Guerin vaccine (BCG) or the infant hexavalent vaccine.

We anticipate a consultation on any proposals relating to these vaccines would occur within in the next three months.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **4 pm Wednesday, 20 November 2013** to:

Therapeutic Group Manager	Email: vaccines@pharmac.govt.nz
PHARMAC	
PO Box 10 254	Fax: 04 460 4995
Wellington 6143	

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive,

confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request **Details of the proposal**

Full technical details of each of the proposed changes relating to vaccines can be found on the PHARMAC website at the following link:
http://www.pharmac.health.nz/news#consultation

All vaccines would be listed in Section H (the Hospital Medicines List) and Section I (the National Immunisation Schedule) of the Pharmaceutical Schedule from 1 July 2014. Sole Subsidised Supply and Hospital Supply status would be applied until 30 June 2017.

The method for ordering vaccines by vaccinators would remain the same. Vaccines would be centrally purchased via PHARMAC's nominated agent (currently the Institute of Environmental Science and Research) and distributed to vaccinators (on receipt of order) twice a month by a nominated distributor (currently Propharma) at no cost to the vaccinator.

The vaccines would be listed Xpharm with a $0.00 subsidy. An Xpharm listing means that pharmacies cannot claim subsidy because PHARMAC has made alternative distribution arrangements. A manufacturer's price would be included in Section I of the Schedule. PHARMAC may have negotiated a lower net purchase price for various vaccines, however these net prices are confidential.

The restrictions applying to all vaccines in Section I would be amended to describe a number of doses rather than the recommended time for administration of vaccines. The Ministry of Health's Immunisation Handbook would provide information to vaccinators on the recommended timing of dosing for particular vaccines and catch up programmes.

Background

PHARMAC began managing the National Immunisation Schedule from 1 July 2012.

Advice has been sought from the Immunisation Subcommittee of PTAC, which is made up of two members of the Pharmacology and Therapeutics Advisory Committee (PHARMAC's main clinical advisors) and the previous Immunisation Technical Forum of the Ministry of Health, about the listing of vaccines.

In June 2013 PHARMAC released a Request for Proposals for the National Immunisation Schedule, which can be found at the following link:
http://www.pharmac.health.nz/news/item/rfp-supply-of-various-vaccines

The proposed listings and amendments to the National Immunisation Schedule are as a result of this RFP process.

PTAC and Immunisation Subcommittee minutes

Minutes from the relevant PTAC and Immunisation Subcommittee minutes are linked below.

The PTAC minutes (related to rotavirus, varicella and human papilloma virus) are from the August PTAC meeting and can be found here:

http://www.pharmac.health.nz/ckeditor_assets/attachments/538/ptac-minutes-2013-08.pdf

The Immunisation Subcommittee minutes can be found here:

March 2013
http://www.pharmac.health.nz/ckeditor_assets/attachments/420/immunisation-subcommittee-minutes-2013-03-06.pdf

April 2013
http://www.pharmac.health.nz/ckeditor_assets/attachments/543/immunisation-subcommittee-minutes-2013-04-23.pdf

Rotavirus vaccine

PHARMAC is seeking feedback on a proposal to list rotavirus vaccine, as a result of a provisional agreement with Merck Sharp & Dohme (New Zealand) Limited.

This proposal would result in the rotavirus vaccine, Rotateq being the only listed rotavirus vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2014 RotaTeq would be listed on the National Immunisation Schedule.

RotaTeq would 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	Manufacturer's price (ex GST)
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	$360.00

A confidential rebate to the manufacturer's price would apply to RotaTeq, reducing the net effect price.

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

Background

The Immunisation Subcommittee reviewed rotavirus vaccines at its March 2013 meeting and recommended the following:

> The Subcommittee **recommended** funding rotavirus vaccination with a high priority.
>
> The Subcommittee further **recommended** a restriction on rotavirus vaccination requiring the first dose to be administered in infants aged under 15 weeks of age and no vaccination being administered to children aged 8 months or over.

PTAC reviewed rotavirus vaccines at its August 2013 meeting and made the following recommendation:

The Committee recommended that a rotavirus vaccine be funded with a medium priority for universal childhood vaccination.

Varicella zoster vaccine

PHARMAC is seeking feedback on a proposal to list varicella zoster vaccine (varicella) as a result of a provisional agreement with GlaxoSmithKline NZ Ltd.

This proposal would result in the varicella vaccine, Varilrix, being the only listed varicella vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2014 Varilrix would be listed on the National Immunisation Schedule.

Varilrix would 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	Manufacturer's price (ex GST)
Varicella-zoster live attenuated vaccine	Injection OKA strain 2000 PFU vial with diluent	Varilrix	1	$0.00	$50.00

PHARMAC has negotiated a lower net purchase price for Varilrix, however this net price is confidential.

Varilrix would 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 would 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 would have sole supply status for 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 would be delisted from Section H from 1 July 2013.

Background

The Immunisation Subcommittee reviewed varicella vaccine at its April 2013 meeting and recommended:

> 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

The Immunisation Subcommittee reviewed varicella vaccine at its March 2013 meeting and recommended:

> The Subcommittee **recommended** the application to fund varicella vaccination for infants as part of the universal childhood vaccination programme with a high priority.
> The Subcommittee **recommended** one dose at 15 months at the same visit as the MMR vaccine (not the MMRV vaccine), with a catch up programme at age 12- 13 years.

PTAC reviewed varicella vaccine at its August 2013 meeting and recommended the following:

> The Committee **recommended** that the application for universal varicella vaccination be declined.
> The Committee **recommended** that varicella vaccination be funded for high risk patients with a high priority
> The Committee **recommended** funding varicella vaccination to prevent transmission to high risk individuals with a high priority.

PTAC noted the following with respect to its recommendation to target high risk patients.

> The Committee considered that varicella vaccine would provide herd immunity and this would provide a significant benefit to those most at risk of varicella infection – the very young and immunocompromised. Members considered the high risk groups identified by the Immunisation Subcommittee would benefit most from a targeted varicella vaccination programme.
>
> The Committee considered that the risks from a universal varicella vaccination programme, i.e. later age of varicella infection in susceptible individuals and a potential increase in herpes zoster in the elderly, would outweigh the benefit of reduction in varicella infection for otherwise healthy individuals. Members considered that the evidence for the effect of varicella vaccination on herpes zoster and age of infection would develop over time. Members noted that a herpes zoster vaccine was registered in New Zealand and an application for this product should be considered as part of the varicella discussion.

As noted in the PTAC minute it is anticipated that further evidence will become available regarding the potential impact of varicella vaccine on zoster infection (shingles). When any new evidence becomes available, PHARMAC will seek the view of its expert clinical advisors.

Pneumococcal conjugate vaccine

PHARMAC is seeking feedback on a proposal to list pneumococcal 13-valent protein conjugate vaccine and delist pneumococcal 10-valent protein conjugate vaccine.

- Pneumococcal 13-valent protein conjugate vaccine (PCV13), Prevenar 13, would be the only listed pneumococcal conjugate vaccine as a result of a provisional agreement with Pfizer New Zealand limited; and

- Pneumococcal 10-valent protein conjugate vaccine (PCV10) Synflorix, would be delisted.

Details of the proposal

Prevenar 13

PHARMAC proposes that from 1 July 2014 Prevenar 13 would be listed on the National Immunisation Schedule. From 1 October 2014 Prevenar 13 would be the only listed pneumococcal conjugate vaccine for the National Immunisation Schedule.

Prevenar 13 would 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	Manufacture's price (excl GST)
Pneumococcal (PVC13) conjugate vaccine	Inj 30.8 mcg in 0.5 ml syringe	Prevenar 13	1	0.00	$145.00
Pneumococcal (PVC13) conjugate vaccine	Inj 30.8 mcg in 0.5 ml syringe	Prevenar 13	10	0.00	$1,450.00

A confidential rebate to the manufacturer's price would apply to all central purchases of Prevenar 13, reducing the net effect price.

Proposed changes

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) would 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.

Synflorix would 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 would be delisted from 1 October 2014.

Prevenar 13 would have sole supply status for both the Community and Hospital settings for pneumococcal conjugate vaccine from 1 October 2014 until 30 June 2017

Background

The Immunisation Subcommittee reviewed pneumococcal conjugate vaccines at its March 2013 meeting and noted the following:

> The Subcommittee noted that if there was an increase in invasive pneumococcal disease caused by the three serotypes not included in PCV10, then the advantage of PCV13 may be greater.

The Subcommittee also reviewed access to pneumococcal vaccine following immunosuppression and recommended the following access be applied:

> 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

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

PHARMAC is seeking feedback on a proposal to amend the listing relating to Meningococcal (Groups A,C,Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine, as a result of a provisional agreement with Sanofi-Aventis New Zealand Limited.

This proposal would result in the Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine, Menactra, being the only listed Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2014 Menactra would be listed on the National Immunisation Schedule.

Menactra would 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	Manufacturer's price (ex GST)
Meningococcal (Groups A,C,Y and W-135) congugate vaccine	Injection 4 µg of each meningococcal polysaccharide conjugated to a total of approximately 48 µg of diphtheria toxoid carrier / 0.5 mL dose	Menactra	1	$0.00	$89.95

PHARMAC has negotiated a lower net purchase price for Menactra, however this net price is confidential.

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

Proposed Changes

From 1 July 2014 meningococcal (groups A, C, Y and W-135) conjugate vaccine and Section I (National Immunisation Schedule) would be listed 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 would 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 would have sole supply status for 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

PHARMAC is seeking feedback on a proposal to list meningococcal C conjugate vaccine, as a result of a provisional agreement with Baxter Healthcare Limited

This proposal would result in the meningococcal conjugate C vaccine (Neisvac-C) being listed as the only meningococcal C conjugate vaccine on the National Immunisation Schedule.

Details of the proposal

PHARMAC proposes that from 1 July 2014 Neisvac-C would be listed on the National Immunisation Schedule.

Neisvac-C would 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	Manufactures price
Meningococcal C conjugate vaccine 10 mcg in 0.5 ml	Injection	Neisvac-C	1	0.00	$22.50
Meningococcal C conjugate vaccine 10 mcg in 0.5 ml	Injection	Neisvac-C	10	0.00	$225.00

Proposal

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

Any of the following:

(a) For patients pre- and post-splenectomy; or
(b) For children aged 0-18 years with functional asplenia; or
(c) For use in transplant patients; or
(d) For use following immunosuppression; or
(e) One dose for close contacts of cases of meningococcal C disease.

Neisvac-C would 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:

(a) For patients pre- and post-splenectomy; or
(b) For children aged 0-18 years with functional asplenia; or
(c) For use in transplant patients; or
(d) For use following immunosuppression; or

(e) For close contacts of cases of meningococcal C disease.

Neisvac-C would have sole supply status for both the Hospital and Community settings for conjugated meningococcal C vaccine from 1 July 2014 until 30 June 2017

Background

The Immunisation Subcommittee reviewed meningococcal conjugate vaccines at its April 2013 meeting and recommended the following:

> 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
>
> The Subcommittee **recommended** with high priority that the restriction should be amended to include children aged 0 to 18 years inclusive with functional asplenia.
>
> 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.
>
> 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.

Consideration of funding for community outbreaks

PHARMAC is considering funding for meningococcal C vaccination for community outbreaks. At this stage outbreak responses would be considered on a case by case application process.

The Immunisation Subcommittee recommended the following with respect to universal meningococcal vaccination:

> 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.
>
> 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.

PHARMAC intends to seek the Immunisation Subcommittee's advice, and present a cost-utility analysis, regarding universal meningococcal C vaccination, in 2014.

Hepatitis A vaccine

PHARMAC is seeking feedback on a proposal to list inactivated hepatitis A vaccine, as a result of a provisional agreement with GlaxoSmithKline NZ Ltd.

This proposal would result in the hepatitis A vaccines, Havrix and Havrix Junior, being the only listed hepatitis A vaccines.

Details of the proposal

PHARMAC proposes that from 1 July 2014 Havrix and Havrix Junior would be listed on the National Immunisation Schedule.

Havrix and Havrix Junior would 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	Manufactures price (ex GST)
Hepatitis A vaccine	Injection 1440 ELISA units in 1 mL	Havrix	1	$0.00	$63.80
Hepatitis A vaccine	Injection720 ELISA units in 0.5 mL	Havrix Junior	1	$0.00	$32.00

PHARMAC has negotiated a lower net purchase price for Havrix and Havrix Junior, however this net price is confidential.

Proposed changes:

Havrix and Havrix Junior would 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.

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

Background

The Immunisation Subcommittee reviewed hepatitis A vaccine at its April 2013 meeting and advised:

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.

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.

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.

PHARMAC is considering funding for hepatitis A vaccination for community outbreaks. At this stage outbreak responses would be considered on a case by case application process.

For the avoidance of doubt the funding for the hepatitis A vaccine for eligible patients in Ashburton, as currently specified in the Pharmaceutical Schedule, would remain funded until at least 30 September 2014. On-going funding of this hepatitis A vaccine for this population would be reviewed prior to removal of funding.

Diphtheria, tetanus and acellular pertussis vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the adult type tetanus, diphtheria, and acellular pertussis vaccine (Tdap) virus vaccine live as a result of a provisional agreement with GlaxoSmithKline NZ Ltd.

In summary, this proposal would result in the Tdap vaccine, Boostrix, being the only listed Tdap vaccine.

Details of the proposal

Boostrix

PHARMAC proposes that from 1 July 2014 Boostrix would remain listed on the National Immunisation Schedule.

Boostrix would 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	Manufacture's price (excl GST)
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	$25.00
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	$250.00

PHARMAC has negotiated a lower net purchase price for Boostrix, however this net price is confidential.

Proposed changes:

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

Funded for either

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.

Note: Tdap is not registered for patients aged less than 10 years.

Boostrix would have sole supply status in both the Community and Hospital settings for Tdap from 1 July 2014 until 30 June 2017.

Background

The Immunisation Subcommittee reviewed Tdap vaccines at its April 2013 meeting and advised:

> 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.

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. Funding for pertussis vaccine during pregnancy will remain unchanged as a result of this current proposal.

Diphtheria, tetanus, acellular pertussis and inactivated polio vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the diphtheria, tetanus, acellular pertussis and inactivated polio vaccine (DTaP-IPV) as a result of a provisional agreement with GlaxoSmithKline NZ Ltd.

This proposal would result in the DTaP-IPV vaccine, Infanrix IPV, being the only listed DTaP-IPV vaccine.

Details of the proposal

Infanrix IPV

PHARMAC proposes that from 1 July 2014 Infanrix IPV would remain listed on the National Immunisation Schedule.

Infanrix IPV would 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	Manufacture's price (excl GST)
Diphtheria, tetanus, pertussis and 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	$400.00

PHARMAC has negotiated a lower net purchase price for Infanrix IPV, however this net price is confidential.

Proposed change

From 1 July 2014 the current restrictions applying to DTaP-IPV would be listed in Section H (the Hospital Medicines List) and remain listed in Section I (National Immunisation Schedule) with the following indication restrictions:

> 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 would have sole supply status in both the Community and Hospital settings for DTaP-IPV from 1 July 2014 until 30 June 2017.

Background

The Immunisation Subcommittee reviewed DTaP IPV vaccine at its April 2013 meeting and recommended the following.

> The Subcommittee **recommended** the following restrictions be applied to diphtheria, tetanus pertussis-containing vaccines (such 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.

The Subcommittee also recommended funding revaccination following immunosuppression.

Hepatitis B vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the hepatitis B vaccine, as a result of a provisional agreement with Merck Sharp & Dohme (New Zealand) Limited.

This proposal would result in hepatitis B vaccine, HBvaxPRO, being the only listed hepatitis B vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2014 three strengths of HBvaxPRO would be listed on the National Immunisation Schedule.

HBvaxPRO would 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	Manufacturer's price (ex GST)
hepatitis B recombinant vaccine	Inj 5 mcg per 0.5 ml vial	HBvaxPRO	1	$0.00	$10.00
hepatitis B recombinant vaccine	Inj 10 mcg per 1 ml vial	HBvaxPRO	1	$0.00	$13.00
hepatitis B recombinant vaccine	Inj 40 mcg per 1 ml vial	HBvaxPRO	1	$0.00	$42.00

PHARMAC has negotiated a lower net purchase price for HBvaxPRO, however this net price is confidential.

Proposed changes

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) would 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:

a) for household or sexual contacts of known hepatitis B carriers; or

b) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or

c) 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

d) for HIV positive patients; or

e) for hepatitis C positive patients; or

f) for patients following immunosuppression; or

g) for transplant patients.

HBvaxPRO 40 mcg vaccine would 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:

a) dialysis patients; or

b) liver or kidney transplant patient;

HBvaxPRO would have sole supply status in both the Community and Hospital settings for hepatitis B vaccine from 1 July 2014 until 30 June 2017.

Background

The Immunisation Subcommittee reviewed hepatitis B vaccines at its April 2013 meeting and recommended that, like all other childhood vaccinations, funding should be made available following immunosuppression.

Inactivated poliomyelitis vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to inactivated poliomyelitis vaccine, as a result of a provisional agreement with Sanofi-Aventis New Zealand limited.

This proposal would result in the inactivated poliomyelitis vaccine, IPOL, being the only listed inactivated poliomyelitis vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2014 IPOL would remain listed on the National Immunisation Schedule.

IPOL would 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	Manufacturer's price (ex GST)
Inactivated poliomyelitis vaccine	Injection 80D antigen units in 0.5 ml	IPOL	1	$0.00	$40.00

PHARMAC has negotiated a lower net purchase price for IPOL, however this net price is confidential.

Proposed Changes

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) would be deleted and replaced with the following indication restrictions:

> Up to three doses for patients meeting either of the following:
>
> (i) For previously unvaccinated individuals; or
>
> (ii) For revaccination following immunosuppression.

IPOL would have sole supply status in both the Community and Hospital settings for inactivated poliomyelitis vaccine from 1 July 2014 until 30 June 2017.

Background

The Immunisation Subcommittee reviewed inactivated poliomyelitis vaccine at its April 2013 meeting and recommended that, as with all other childhood vaccinations, funding should be made available following immunosuppression.

Human papilloma virus vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the human papilloma virus (HVP) vaccine, as a result of a provisional agreement with bioCSL (NZ) Ltd.

This proposal would result in the HPV vaccine, Gardasil, being the only listed HPV vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2014 Gardasil would remain listed on the National Immunisation Schedule.

HPV vaccine would 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	Manufacturer's price (ex GST)
Human papilloma virus (6,11,16 and 18)	Injection 120 mcg in 0.5 ml	Gardasil	10	$0.00	$1,285.00

PHARMAC has negotiated a lower net purchase price for Gardasil, however this net price is confidential.
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Proposed Changes

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

> Maximum of three doses for patient meeting any of the following criteria:
> (i) Women aged under 18 years old; or
> (ii) Male patients aged under 25 years old with confirmed HIV infection; or
> (iii) For use in transplant patients.

It is proposed that girls born in birth cohorts 1994, 1995, 1996 and 1997 would have until the 31 December 2014 to commence the HPV programme and would be funded to complete the programme if they commenced it before 31 December 2014.

Gardasil would have sole supply status in both the Community and Hospital settings for HPV vaccine from 1 July 2014 until 30 June 2017.

Background

PTAC reviewed HPV vaccine at its August 2013 meeting.
The Immunisation Subcommittee reviewed HPV vaccine at its March 2013 meeting.

Adult diphtheria and tetanus vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the adult diphtheria and tetanus (Td) vaccine as a result of a provisional agreement with bioCSL (NZ) Ltd.

This proposal would result in the Td vaccine, ADT Booster, being the only listed Td vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2014 ADT Booster would remain listed on the National Immunisation Schedule.

Td vaccine would 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	Manufacturer's price (ex GST)
Adult diphtheria and tetanus	Injection 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml	ADT Booster	5	$0.00	$84.83

PHARMAC has negotiated a lower net purchase price for ADT Booster, however this net price is confidential.

Proposed Changes

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

> Any of the following:
>
> a) For vaccination of patients aged 45 and 65 years old; or
>
> b) For vaccination of previously unimmunised patients; or
>
> c) For revaccination following immunosuppression; or
>
> d) For revaccination for patients with tetanus-prone wounds; or
>
> e) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

ADT Booster would 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

PHARMAC is seeking feedback on a proposal to amend the listing relating to the measles, mumps, and rubella (MMR) virus vaccine live, as a result of a provisional agreement with Merck Sharp & Dohme (New Zealand) Limited.

This proposal would result in the MMR vaccine, MMR-II, being the only listed MMR vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2014 MMR-II would remain listed on the National Immunisation Schedule.

MMR would 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	Manufacturer's price (ex GST)
Measles, mumps and rubella vaccine	Injection 1000 TCID50 measles, 12500 TCID50 mumps and 1000 TCID50 rubella vial with diluent 0.5 mL	M-M-R-II	10	$0.00	$140.00

PHARMAC has negotiated a lower net purchase price for M-M-R-II, however this net price is confidential.

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Proposed Changes

From 1 July 2014 the current restriction applying to MMR vaccines in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule) would 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

MMR-II would have sole supply status in both the Community and Hospital settings for MMR from 1 July 2014 until 30 June 2017.

Background

The Immunisation Subcommittee reviewed MMR vaccines at its April 2013 meeting and recommended that, like all other childhood vaccinations, funding should be made available following immunosuppression.

Pneumococcal polysaccharide vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the pneumococcal polyvalent vaccine, as a result of a provisional agreement with Merck Sharp & Dohme (New Zealand) Limited.

This proposal would result in the pneumococcal polyvalent vaccine, Pneumovax 23 being the only listed pneumococcal polysaccharide vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2014 Pneumovax 23 would remain listed as the pneumococcal polyvalent polysaccharide vaccine for the National Immunisation Schedule.

Pneumovax 23 would 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	Manufactures price
Pneumococcal (PPV23) polysaccharide vaccine Inj 575 mcg in 0.5 ml	Vial	Pneumovax 23	1	$0.00	$35.26

PHARMAC has negotiated a lower net purchase price for Pneumovax 23, however this net price is confidential.

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Proposed changes

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) would be deleted and replaced with the following indication restrictions:

> Either of the following:
> (i) Up to three doses for patients pre- or post-splenectomy or with functional asplenia; or
> (ii) Up to two doses are funded for high risk children to the age of 18.

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

Background

The Immunisation Subcommittee reviewed pneumococcal polysaccharide vaccines at its April 2013 meeting and advised:

> 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