CONSULTATION

PHARMAC
Pharmaceutical Management Agency

30 May 2016

Proposal to amend listings in the National Immunisation Schedule

Following a Request for Proposals (RFP) for the supply of various vaccines, issued on 15 February 2016, PHARMAC is now 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. In summary, these proposals would result in the following access, brand & dose changes:

From 1 January 2017:

- **Human papillomavirus (HPV) vaccine**
  - Funded access would be widened to include males and females aged 26 years old and under.
  - A two-dose regimen would be funded rather than a three-dose regimen for those males and females aged 14 and under. This would be subject to Medsafe approval of the two-dose regimen.
  - A three-dose schedule for males and females aged 15-26 years.
  - The 4 valent (Gardasil) HPV vaccine would be replaced with the 9 valent (Gardasil 9) vaccine.
  - Females who have started a three-dose regimen of Gardasil would be able to complete their remaining doses in 2017.

From 1 July 2017:

- **Varicella vaccine**
  - Funded access would be widened to include one dose for primary vaccination in children at 15 months old and a catch up in general practice of one dose for unvaccinated children aged 11 years, who have not previously been vaccinated against varicella or contracted chickenpox.
  - Funding criteria for high risk patients would remain unchanged.

- **Pneumococcal conjugated vaccine (PCV)**
  - The 13 valent (Prevenar 13) pneumococcal vaccine would be replaced with the 10 valent (Synflorix) PCV10 vaccine on the National Immunisation Schedule.
  - Prevenar 13 would remain available for high risk patients only.

- **Rotavirus vaccine**
  - The currently listed RotaTeq brand would be replaced with the Rotarix brand.
  - The current three-dose regimen would be replaced with a two-dose regimen.

- **Measles, mumps and rubella vaccine**
  - The currently listed MMR-II brand would be replaced with the Priorix brand.

- ***Haemophilus influenzae* type B (Hib) vaccine**
  - The currently listed Act-Hib brand would be replaced with the Hiberix brand.

Provisional agreements have been reached with the following suppliers:

- **Seqirus (NZ) Limited (Seqirus)**
  - adult diphtheria and tetanus vaccine (ADT Booster); and
  - human papillomavirus vaccine (Gardasil 9).

- **GlaxoSmithKline NZ Limited (GlaxoSmithKline)**
  - diphtheria, tetanus and acellular pertussis vaccine (Boostrix);
  - diphtheria, tetanus, acellular pertussis and inactivated polio vaccine (Infanrix IPV);
  - diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine (Infanrix Hexa);
  - varicella-zoster vaccine (Varilrix);
  - pneumococcal (PCV10) vaccine (Synflorix);
  - measles, mumps and rubella vaccine (Priorix);
  - haemophilus influenzae type B vaccine (Hiberix); and
  - rotavirus vaccine (Rotarix).

All contracted vaccines would have Sole Supply Status from 1 July 2017 until 30 June 2020, making them the only vaccines listed for use in both the community and DHB hospitals.

At this time PHARMAC has not finalised provisional agreements for the following:

- Bacillus Calmette-Guerin vaccine (BCG);
- meningococcal C conjugate vaccine;
- hepatitis A vaccine;
- hepatitis B recombinant vaccine;
- pneumococcal polyvalent vaccine;
- poliomyelitis vaccine;
- pneumococcal (PCV13) vaccine (for high risk patients);
- meningococcal A, C , Y and W135 vaccine; and
- tuberculin PPD (Mantoux) test (Tubersol).

We anticipate a consultation on proposals relating to the above products will be issued within the next three months.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5 pm Monday, 20 June 2016** to:

Matthew Wolfenden	Email: vaccines@pharmac.govt.nz
Procurement Manager	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, 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

Background

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

PHARMAC first issued an RFP for the supply of vaccines in June 2013, which resulted in agreements with five suppliers. Sole Supply Status for vaccines covered by those agreements expires on 30 June 2017.

In preparation for running an RFP, PHARMAC requested that suppliers submit applications to PHARMAC for:

- funding of any new or alternative brands of vaccines they may have available for supply from July 2017; and
- any proposed changes to the funding eligibility criteria for current listings and/or the National Immunisation Schedule.

PHARMAC subsequently sought clinical advice from the Immunisation Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) on:

- the suitability of new vaccines recently registered by Medsafe or planned to be registered in time for 2017 supply;
- interchangeability of alternative brands; and
- possible funding eligibility criteria changes.

The complete Immunisation Subcommittee minutes are available on our website at:

www.pharmac.health.nz/about/committees/ptac/ptac-subcommittees/

On 15 February 2016 PHARMAC released an RFP for the supply of various vaccines, which can be found at the following link:

www.pharmac.govt.nz/news/rfp-2016-02-16-supply-of-various-vaccines/

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

Distribution of Vaccines unchanged

Vaccines are distributed differently to most other pharmaceuticals. The method for ordering vaccines by vaccinators would remain the same as a result of this proposal.

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.

Details of the proposals

Gardasil 9 would be listed in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 January 2017. All the other vaccines set out in this proposal would be listed in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2017.

PHARMAC would use its reasonable endeavours to ensure the funded Pharmaceuticals are the only brand of the Pharmaceuticals distributed by the Service Provider on or after 1 July 2017.

Confidential net prices would apply to all vaccines listed as a result of this RFP.

The current funding criteria applying to all vaccines can be found in **Section I** and **Section H** of the Pharmaceutical Schedule and would be amended to implement any changes to eligibility and/or the number of doses, should these proposals be accepted.

The current funding criteria and the proposed amendments are collated in **Annex A** of this document.

The Ministry of Health's Immunisation Handbook would continue to provide information to vaccinators on the recommended timing of dosing for particular vaccines and catch up programmes.

Further details about each of the vaccines and proposed changes are set out below as follows:

Human papilloma virus vaccine

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

This proposal would result in a change of HPV vaccine from Gardasil which contains 4 HPV antigens (types 6, 11, 16, 18) to Gardasil 9 which contains 9 HPV antigens (types 6, 11, 16, 18, 31, 33, 45, 52 and 58).

Gardasil 9 is currently registered for use under a three-dose regimen, the same as Gardasil. A Changed Medicine Notification has been lodged with Medsafe to change the regimen from three doses to two doses for children aged 14 years and under.

Details of the proposal

PHARMAC proposes that from 1 January 2017 Gardasil 9 would be listed on the National Immunisation Schedule. Gardasil would be delisted from 1 July 2017.

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacturer's price (ex GST)
human papilloma virus (6, 11, 16, 18, 31, 33, 45, 52 and 58)	Injection 270 mcg in 0.5 ml	Gardasil 9	10	$0.00	$1,415.00
Human papilloma virus (6,11,16 and 18)	Injection 120 mcg in 0.5 ml	Gardasil	10	$0.00	$1,285.00

A confidential discount would apply, reducing the net price of the product to the Funder.

Proposed Changes

From 1 January 2017 the funding restrictions 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:

1. Maximum of two doses for males and females aged 14 years and under; or
2. Maximum of three doses for patients meeting any of the following criteria:

    i. Male and female patients aged 26 years and under; or

    ii. For use in transplant (including stem cell) patients: or

    iii. An additional dose for patients under 26 years of age post chemotherapy.

The criteria proposed above assume market approval of the Gardasil 9 two dose regimen prior to 1 January 2017. Progression would be subject to Medsafe approval of the two-dose regimen.

Gardasil 9 would have Sole Supply Status in both the community and DHB hospital settings for HPV vaccine from 1 July 2017 until 30 June 2020.

Background

The human papillomavirus virus (HPV) causes a number of cancers with cervical cancer being the most prevalent. Approximately 70% of cervical cancers are caused by HPV types 16 and 18 (covered by the four antigen Gardasil, "Gardasil") while a further 20% are caused by 31, 33, 45, 52 and 58 (covered by the antigens contained in Gardasil 9). HPV vaccination also protects against a number of other cancers including anal, penile, vulval, vaginal, and some forms of oropharyngeal cancers.

In response to the RFP issued in February 2016, Seqirus has proposed supply of the 9 antigen Gardasil 9 which is registered for use under a 3 dose regimen, the same as Gardasil. A Changed Medicine Notification has been lodged with Medsafe to change the regimen for 3 doses to two doses for those children aged 14 years and under.

Clinical trials have reported Gardasil 9 to be non-inferior to Gardasil in relation to the four antigens they have in common (6, 11, 16 and 18). While results from the two dose studies have reported that doses given at both 0 and 6 months (girls and boys) and 0 and 12 months (girls and boys) achieve good seroconversion, the 0 and 12 month schedule is recommended by the supplier as it achieves a higher seroconversion (access to two dose trial work can be found at www.clinicaltrials.gov).

Both the Immunisation Subcommittee (March 2013) and PTAC itself (August 2013) have reviewed an application from the supplier for funded access to be widened to young males aged 12 years and older to match the current National Immunisation Schedule funded access for girls. Full minutes of these meetings can be found at:

www.pharmac.govt.nz/assets/ptac-immunisation-subcommittee-minutes-2013-03-06.pdf

www.pharmac.govt.nz/assets/ptac-minutes-2013-08.pdf

Both the Subcommittee and PTAC made the following recommendations:

- that the age of female vaccination be amended to allow the first dose at age 11 with a medium priority, and allow the school based program to be initiated in year seven rather than year eight.
- widening access to HPV vaccine to include males between the ages of 11 and 25 inclusive who identify as MSM with a high priority.
- widening access to HPV vaccine to include all males between the ages of 11 and 18 with a low priority.

Two dose vaccination schedule

In February 2015, the Immunisation Subcommittee reviewed a PHARMAC-generated proposal to fund a two dose regimen for Gardasil (the 4 antigen preparation). Full minutes of the meeting can be found at:

www.pharmac.govt.nz/assets/ptac-immunisation-subcommittee-minutes-2015-02-18.pdf

- The Subcommittee recommended funding two-dose HPV vaccination for girls up to 15 years of age, with a high priority noting that the three-dose HPV vaccination would remain funded for girls over 15 years of age.

This recommendation would have been difficult to implement as, at that time, Gardasil was not registered for a two dose regimen and the supplier did not have an appropriate registration dossier.

If the changed medicine notification to change the registration for Gardasil 9 is approved, this proposal would enable the introduction of a two-dose regimen to year 8 girls and boys in the 2017 school year with the possibility of moving to Year 7 boys and girls at a timing determined by the Ministry of Health, which is responsible for the in-school programme. If the move to year 7 was made, year 8 boys and girls would also need to be vaccinated in the same year.

Varicella vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to varicella vaccine (varicella) as a result of a provisional agreement with GlaxoSmithKline.

This proposal would result in the Varilrix being the only listed varicella vaccine. Funding restrictions would be widened to include:

- Primary vaccination in children, one dose, at 15 months; and
- A catch up in general practice of one dose for unvaccinated children aged 11 years, who have not previously been vaccinated against varicella or contracted chickenpox; and
- Funded access for patients considered to be at high risk of infection (as currently defined in the Pharmaceutical Schedule) would continue.

Details of the proposal

PHARMAC proposes that from 1 July 2017 Varilrix would remain listed on the National Immunisation Schedule.

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacturer's price (ex GST)
Varicella vaccine	Inj 2000 PFU pre-filled syringe plus vial	Varilrix	1	$0.00	$50.00
Varicella vaccine	Inj 2000 PFU pre-filled syringe plus vial	Varilrix	10	$0.00	$500.00

A confidential discount would apply, reducing the net price of the product to the Funder.

Proposed changes

Varilrix would be listed in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2017 with the following amendments to restrictions shown in bold:

1. One dose for primary vaccination for:

i. **Children at 15 months; or**

ii. **For previously unvaccinated children at 11 years old, who have not previously had a varicella infection (chickenpox).**

2. Maximum of two doses for any of the following:

i. For non-immune patients:

(a) with chronic liver disease who may in future be candidates for transplantation; or
(b) with deteriorating renal function before transplantation; or
(c) prior to solid organ transplant; or
(d) prior to any elective immunosuppression*.

ii. For patients at least 2 years after bone marrow transplantation, on advice of their specialist.

iii. For patients at least 6 months after completion of chemotherapy, on advice of their specialist.

iv. For HIV positive patients non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist.

v. For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella.

vi. For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

vii. For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

* 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 in both the community and DHB hospital settings for varicella vaccine from 1 July 2017 until 30 June 2020.

Background

Varilrix has been listed and funded for patients at high risk of infection since 1 July 2014. Usage under the current funding criteria is less than 1000 doses per year.

This proposal is to introduce varicella vaccination into the National Immunisation Schedule initially with one dose being given at 15 months. A catch-up dose in general practice at 11 or 12 years would be funded for patients who have not had chickenpox previously and who have not been vaccinated against chickenpox.

Chickenpox is perceived as being a mild disease and most often is. However, complications such as secondary bacterial infection, pneumonitis and encephalitis occur in about 1% of cases, more typically in young adults, and usually lead to hospitalisation.

A study by Wen et al (Prospective surveillance of hospitalisations associated with varicella in New Zealand: J. Paediatr. Child Health 2015 doi:10.1111/jpc.12937) reported an annual incidence in New Zealand of varicella-related hospitalisations of 8.3/100,000 children (95% confidence interval 7.0-9.8/100,000) between 1 November 2011 and 31 October 2013. Complications included infection (75%), respiratory (11%), electrolyte disturbance (6%) and haemorrhagic varicella (4%) and 19% had ongoing problems at discharge. Māori and Pacific Island children accounted for 74% of the hospitalisations.

A ten year (2001-2011) review by Wen et al of varicella admissions to the Paediatric Intensive Care Unit at Starship Hospital (J. Paediatr. Child Health 2014;50(4):280-5) identified 34 cases, of which 26 patients were included in the review. Of these patients admission reasons were neurological (38.5%), secondary bacterial sepsis or shock (26.9%), respiratory (15.4%), disseminated varicella (11.5%), or other causes (7.7%). Four children died, three of whom, were immunocompromised and 31% had ongoing disability after discharge.

The Immunisation Subcommittee reviewed varicella vaccine at its March 2013 meeting and PTAC reviewed varicella vaccine at its August 2013 meeting. Full minutes of these meetings can be found at:

www.pharmac.govt.nz/assets/ptac-immunisation-subcommittee-minutes-2013-03-06.pdf

www.pharmac.govt.nz/assets/ptac-minutes-2013-08.pdf

Most recently, PTAC reviewed varicella vaccine at its February 2015 meeting and recommended:

- Varicella vaccine be funded with a high priority as a part of a universal childhood immunisation.
- The Committee noted that varicella vaccine could be given in combination with the HiB, MMR and pneumococcal vaccine at 15 months.
- While some members of the Committee considered that introducing a fourth injectable vaccine at 15 months could be problematic the majority of the Committee considered that it is acceptable to give four injections at that time.
- The Committee noted that for vaccination against varicella to be effective, patients would eventually require two doses, as wild-type varicella incidence in the paediatric population decreases.
- The Committee recommended Varicella vaccine be listed on the Pharmaceutical Schedule funded for one infant dose at age 15 months and one catch up dose at 11 or 12 years of age, with a high priority. One member abstained from voting.

Full minutes of the meeting can be found at:

www.pharmac.govt.nz/assets/ptac-immunisation-subcommittee-minutes-2015-02-18.pdf

Pneumococcal conjugate vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating for pneumococcal conjugate vaccine (PCV) as a result of a provisional agreement with GlaxoSmithKline.

This proposal would result in:

- Synflorix, pneumococcal 10-valent protein conjugate vaccine (PCV10), being listed and replacing Prevenar 13 (PCV13) under the following criteria:
    - the primary course of immunisation for previously unvaccinated individuals up to the age of 59 months;
    - individuals under the age of 59 months who have not completed a four dose primary course of immunisation of PCV13; and
    - testing for primary immunodeficiency diseases.

An agreement for Prevenar 13, pneumococcal 13-valent protein conjugate vaccine (PCV13), for high risk patients only, has not been finalised.

Details of the proposal

PHARMAC proposes that from 1 July 2017 Synflorix would be listed on the National Immunisation Schedule.

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacturer's price (ex GST)
Pneumococcal (PVC10) conjugate vaccine	Inj 1mcg of pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14 and 23F; 3mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5ml prefilled syringe	Synflorix	10	$0.00	$1,400.00

A confidential discount would apply, reducing the net price of the product to the Funder.

Proposed changes

Synflorix, pneumococcal (PCV10) vaccine, would be the only pneumococcal vaccine listed in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2017 for funding under the following 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 PCV13; or

3) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Synflorix would have Sole Supply Status in both the community and DHB hospital settings for pneumococcal conjugate vaccine from 1 July 2017 until 30 June 2020.

Background

The Immunisation Subcommittee reviewed pneumococcal conjugate vaccines at its October 2015 meeting and **noted** the following:

> The Subcommittee considered that both PCV10 (GSK's Synflorix) and PCV13 (Pfizer's Prevenar 13) are suitable for inclusion on the National Immunisation Schedule but that if PCV10 were listed for universal vaccination it may be necessary to continue to list PCV13 for vaccination of high risk groups.

Full minutes of the meeting can be found at:

www.pharmac.govt.nz/assets/ptac-immunisation-subcommittee-minutes-2015-10.pdf

Since the October 2015 meeting, GlaxoSmithKline has gained approval from Medsafe for an indication for active immunisation against disease caused by cross-reactive serotype 19A. At its' May 2016 meeting, the Immunisation Subcommittee recommended that PHARMAC monitor the incidence of 19A related invasive pneumococcal disease as reported in the ESR quarterly surveillance reports.

Rotavirus vaccine

PHARMAC is seeking feedback on a proposal to list an alternative brand of rotavirus, as a result of a provisional agreement with GlaxoSmithKline.

This proposal would result in Rotarix being the only listed rotavirus vaccine, RotaTeq being delisted and the current three-dose regimen being replaced with a two-dose regimen.

Details of the proposal

PHARMAC proposes that from 1 July 2017 Rotarix would be listed on the National Immunisation Schedule.

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacturer's price (ex GST)
Rotavirus vaccine	Pre-filled oral applicator, live attenuated human rotavirus 1,000,000 $CCID_{50}$ per dose	Rotarix	10	$0.00	$400.00

A confidential discount would apply, reducing the net price of the product to the Funder.

Rotarix would be listed in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2017 with the following amended funding restrictions (deletions in strike through, insertions in bold):

> Maximum of ~~three~~ **two** doses for patients meeting the following:
> 1. first dose to be administered in infants aged under ~~15~~ **14** weeks of age; and
> 2. no vaccination being administered to children aged ~~8 months~~ **24 weeks** or over.

Rotarix would have Sole Supply Status in both the community and DHB hospital settings for rotavirus vaccine from 1 July 2017 until 30 June 2020.

Background

Rotavirus vaccine has been listed and funded for primary vaccination in children since 1 July 2014. The Immunisation Subcommittee reviewed rotavirus vaccines at its March 2013 meeting and recommended:

- Funding rotavirus vaccination with a high priority.
- The Subcommittee considered that the two commercially available vaccines (Rotarix and RotaTeq) were of equal efficacy and PHARMAC could consider the Subcommittee's considerations as applying equally to both vaccines. Members considered that the two vaccines had a same or similar clinical efficacy. Members considered that the evidence for RotaTeq did not support any improved clinical outcomes as a result of the G2 strain inclusion. Members considered that there was cross-protection between strains from vaccine or illness, but that it was not complete.
- The Subcommittee noted that both vaccines were oral and can be given as part of the existing vaccine schedule. Members considered that the approved dosing frequency, either 2 or 3 doses, of each vaccine would be appropriate for the New Zealand setting.

Full minutes of these meetings can be found at:

www.pharmac.govt.nz/assets/ptac-immunisation-subcommittee-minutes-2013-03-06.pdf

Measles, mumps and rubella vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the measles, mumps, and rubella (MMR) vaccine, as a result of a provisional agreement with GlaxoSmithKline.

This proposal would result in Priorix being the only listed MMR vaccine and M-M-R II being delisted.

Details of the proposal

PHARMAC proposes that from 1 July 2017 Priorix would be listed on the National Immunisation Schedule.

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacturer's price (ex GST)
Measles, mumps and rubella vaccine	Injection, measles virus 1,000 $CCID_{50}$, mumps virus 5,012 $CCID_{50}$, Rubella virus 1,000 $CCID_{50}$; prefilled syringe/ampoule of diluent 0.5 ml	Priorix	10	$0.00	$250.00

A confidential discount would apply, reducing the net price of the product to the Funder.

Proposed Changes

From 1 July 2017 the MMR vaccine would continue to be listed, with no change to the current funding restrictions in Section I or Part II Section H of the Pharmaceutical Schedule.

Priorix would have Sole Supply Status in both the community and DHB hospital settings for MMR from 1 July 2017 until 30 June 2020.

Haemophilus influenzae type B vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the *Haemophilus influenzae* type B vaccine, as a result of a provisional agreement with GlaxoSmithKline.

This proposal would result in Hiberix being the only listed *haemophilus influenzae* type B vaccine; Act-HIB would be delisted.

Details of the proposal

PHARMAC proposes that from 1 July 2017 Hiberix would be listed on the National Immunisation Schedule.

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacturer's price (ex GST)
Haemophilus influenzae type B vaccine	Haemophilus Influenzae type b polysaccharide 10 mcg conjugated to tetanus toxoid as carrier protein 20-40 mcg; pre-filled syringe plus vial 0.5 ml	Hiberix	10	$0.00	$200.00

A confidential discount would apply, reducing the net price of the product to the Funder.

Proposed changes

From 1 July 2017 the *Haemophilus influenzae* type B vaccine would be listed, with no change to the current funding restrictions in Section I or Part II Section H of the Pharmaceutical Schedule.

Hiberix would have Sole Supply Status in both the community and DHB hospital settings for *Haemophilus influenzae* type B vaccine from 1 July 2017 until 30 June 2020.

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.

This proposal would result in Boostrix remaining as the only listed Tdap vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2017 Boostrix would remain listed on the National Immunisation Schedule.

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacturer's price (ex GST)
Diphtheria, tetanus and acellular 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 pre-filled syringe	Boostrix	1	$0.00	$25.00
Diphtheria, tetanus and acellular 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 pre-filled syringe	Boostrix	10	$0.00	$250.00

A confidential discount would apply, reducing the net price of the product to the Funder.

Proposed changes:

From 1 July 2017 adult type tetanus, diphtheria, and acellular pertussis vaccine would be listed with no change to the current funding restrictions in Section I or Part II Section H of the Pharmaceutical Schedule.

Boostrix would have Sole Supply Status in both the community and DHB hospital settings for Tdap from 1 July 2017 until 30 June 2020.

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.

This proposal would result in Infanrix IPV remaining as the only listed DTaP-IPV vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2017 Infanrix IPV would remain listed on the National Immunisation Schedule.

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacture's price (ex 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 pre-filled syringe	Infanrix IPV	10	$0.00	$400.00

A confidential discount would apply, reducing the net price of the product to the Funder.

Proposed change

From 1 July 2017 diphtheria, tetanus, acellular pertussis and inactivated polio vaccine would be listed with no change to the current funding restrictions in Section I or Part II Section H of the Pharmaceutical Schedule.

Infanrix IPV would have Sole Supply Status in both the community and DHB hospital settings for DTaP-IPV from 1 July 2017 until 30 June 2020.

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

PHARMAC is seeking feedback on a proposal to amend the listing relating to the adult type diphtheria, tetanus, acellular pertussis, inactivated polio, *Haemophilus influenzae* type B and hepatitis B vaccine virus vaccine live (hexavalent vaccine) as a result of a provisional agreement with GlaxoSmithKline.

This proposal would result in Infanrix-Hexa remaining as the only listed hexavalent vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2017 Infanrix-Hexa would remain listed on the National Immunisation Schedule.

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacture's price (ex GST)
Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine	Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagluttinin, 8 mcg pertactin, 80 D-antigen units poliomyelitis virus, 10 mcg hepatitis B surface antigen in 0.5 ml syringe (1) and 10 mcg haemophilus influenza type B vaccine in 0.5 ml pre-filled syringe	Infanrix Hexa	10	$0.00	$1,300.00

A confidential discount would apply, reducing the net price of the product to the Funder.

Proposed changes:

From 1 July 2017 the hexavalent vaccine would be listed with no change to the current funding restrictions in Section I or Part II Section H of the Pharmaceutical Schedule.

Infanrix-Hexa would have Sole Supply Status in both the community and DHB hospital settings for the hexavalent vaccine from 1 July 2017 until 30 June 2020.

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 Seqirus.

This proposal would result in ADT Booster remaining as the only listed Td vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2017 ADT Booster would remain listed on the National Immunisation Schedule.

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	$84.85

A confidential discount would apply, reducing the net price of the product to the Funder.

Proposed Changes

From 1 July 2017 adult diphtheria and tetanus vaccine would be listed with no change to the current funding restrictions in Section I or Part II Section H of the Pharmaceutical Schedule.

ADT Booster would have Sole Supply Status in both the community and DHB hospital settings for Td vaccine from 1 July 2017 until 30 June 2020.

Annex A – Current and Proposed Funding Criteria

The following funding criteria would apply (amendments/additions are shown in bold and deletions in strike through):

Adult diphtheria and tetanus vaccine – ADT Booster

Any of the following:

1. For vaccination of patients aged 45 and 65 years old; or
2. For vaccination of previously unimmunised or partially immunised patients; or
3. For revaccination following immunosuppression; or
4. For boosting of 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.

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

Diphtheria, tetanus and acellular pertussis vaccine – Boostrix

Funded for any of the following criteria:

1. A single vaccine for pregnant woman between gestational weeks 28 and 38; or
2. A course of up to four vaccines is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or
3. An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens.

Notes: Tdap is not registered for patients aged less than 10 years. Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Diphtheria, tetanus, acellular pertussis and inactivated polio vaccine – Infanrix IPV

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 four vaccines is funded for catch up programmes for children (to the age of 10 years) to complete full primary immunisation; or
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; or
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.

Diphtheria, tetanus, acellular pertussis, inactivated polio, *Haemophilus influenzae* type B and hepatitis B vaccine – Infanrix Hexa

Funded for patients meeting any of the following criteria:

1. Up to four doses for children up to and under the age of 10 for primary immunisation; or

2. An additional four doses (as appropriate) are funded for (re-)immunisation for children up to and under the age of 10 who are patients post haematopoietic stem cell transplantation, or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or

3. Up to five doses for children up to and under the age of 10 receiving solid organ transplantation

Note: A course of up-to four vaccines is funded for catch up programmes for children (up to and under the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

Haemophilus influenzae type B vaccine – Hiberix

One dose for patients meeting any of the following:

1. For primary vaccination in children; or

2. An additional dose (as appropriate) is funded for (re-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; functional asplenic; pre or post splenectomy; pre- or post solid organ transplant, pre- or post cochlear implants, renal dialysis and other severely immunosuppressive regimens; or

3. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Human papillomavirus vaccine – Gardasil 9

1. **Maximum of two doses for males and females aged 14 years and under; or**

2. Maximum of three doses for patient**s** meeting any of the following criteria:

    i. **Male and** female~~s~~ **patients** ~~aged under 20 years old~~ **26 years and under**; or

    ~~Patients aged under 26 years old with confirmed HIV infection; or~~

    ii. For use in transplant (including stem cell) patients; or

    iii. An additional dose for patients under 26 years of age post chemotherapy.

The criteria proposed above assume market approval of the Gardasil 9 two dose schedule prior to listing on the Pharmaceutical Schedule.

Measles, mumps and rubella vaccine – Priorix

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; or

4. A maximum of three doses for children who have had their first dose prior to 12 months.

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

Pneumococcal (PCV10) vaccine – Synflorix

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 PCV13; or**

3. **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

Rotavirus vaccine – Rotarix

Maximum of three two doses for patients meeting the following:

1. First dose to be administered in infants aged under ~~**15**~~ **14** weeks of age; and

2. no vaccination being administered to children aged ~~**8 months**~~ **24 weeks** or over.

Varicella vaccine – Varilrix

1. **One dose for primary vaccination for:**

   i. Children at 15 months; or

   ii. For previously unvaccinated children at 11 years old, who have not previously had a varicella infection (chickenpox).

2. Maximum of two doses for any of the following:

   i. For non-immune patients:

   (a) with chronic liver disease who may in future be candidates for transplantation; or
   (b) with deteriorating renal function before transplantation; or
   (c) prior to solid organ transplant; or
   (d) prior to any elective immunosuppression*.

   ii. For patients at least 2 years after bone marrow transplantation, on advice of their specialist.

   iii. For patients at least 6 months after completion of chemotherapy, on advice of their specialist.

   iv. For HIV positive patients non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist.

   v. For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella.

   vi. For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

   vii. For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

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