Proposal to amend listings in the National Immunisation Schedule

9 December 2016

Following a Request for Proposals (RFP) for the supply of various vaccines, issued on 15 February 2016, PHARMAC has previously consulted on and notified of decisions relating to the following vaccines:

- Human papillomavirus (HPV) vaccine
- Adult diphtheria and tetanus vaccine
- Varicella vaccine
- Pneumococcal conjugated (PCV10) vaccine
- Rotavirus vaccine
- Measles, mumps and rubella vaccine
- *Haemophilus influenzae* type B (Hib) vaccine
- Diphtheria, tetanus and pertussis vaccine
- Diphtheria, tetanus, pertussis and inactivated polio vaccine
- Diphtheria, tetanus, pertussis, polio, hepatitis B and *haemophilus influenzae* type B vaccine

PHARMAC is seeking feedback on further proposals arising from the RFP, relating to provisional agreements with a number of suppliers, for the supply of vaccines from 1 July 2017 for the New Zealand National Immunisation Schedule. In summary, the proposed changes include:

- **Pneumococcal conjugated (PCV13) vaccine**
  - Re-instating the eligibility criteria for high-risk children aged less than 5 years.

- **Varicella vaccine**
  - Proposed minor clarification amendment to eligibility criteria.

- ***Haemophilus influenzae* type B (Hib) vaccine**
  - GlaxoSmithKline has notified PHARMAC of a change in pack size for the Hiberix brand from 10 injections to a single injection per pack. There would be no change to the price per injection.

- **Brand switch transition periods introduced**
  - All of the GlaxoSmithKline vaccines would have Sole Supply Status from 1 September 2017 until 30 June 2020. This is a proposed change from 1 July 2017, and would provide a transition period between 1 July and 31 August 2017 for the introduction of the following vaccines:
    - Pneumococcal (PCV10) vaccine (Synflorix);
    - Measles, mumps and rubella vaccine (Priorix);
    - *Haemophilus influenzae* type B vaccine (Hiberix); and
    - Rotavirus vaccine (Rotarix).

- **Minor clarifications to special authority criteria for the following vaccines:**
  - Hepatitis B recombinant vaccine
  - Pneumococcal (PPV23) polysaccharide vaccine

- **Tuberculin purified protein derivative (Mantoux) test**
  - The Tubersol brand would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule
Provisional agreements have been reached with the following suppliers:

- **Merck Sharp & Dohme (New Zealand) Limited (MSD)**
  - Hepatitis B recombinant vaccine (HBvaxPRO – 5 mcg, 10 mcg & 40 mcg); and
  - Pneumococcal polyvalent vaccine (Pneumovax 23).

- **Sanofi-Aventis New Zealand Limited (Sanofi)**
  - Poliomyelitis vaccine (IPOL);
  - Meningococcal A, C, Y and W135 conjugate vaccine (Menactra); and
  - Tuberculin PPD (mantoux) test (Tubersol).

- **GlaxoSmithKline NZ Limited (GlaxoSmithKline)**
  - Hepatitis A vaccine (Havrix and Havrix Junior).

All contracted vaccines would have Sole Supply Status in both the community and DHB hospitals.

At this time PHARMAC has not finalised a provisional agreement for Meningococcal C conjugate vaccine.

**Feedback sought**

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5 pm Friday, 20 January 2017** to:

Matthew Wolfenden  
Procurement Manager  
PHARMAC

Email: vaccines@pharmac.govt.nz  
Fax: 04 460 4995  
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.
Details of the proposals

All of the 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.

Confidential net prices would apply to some 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 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:

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<td>Pneumococcal (PPV23) polysaccharide vaccine</td>
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<td>Poliomyelitis vaccine</td>
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</table>
Pneumococcal conjugated (PCV13) vaccine

Historically, when PCV7 and PCV10 were listed for universal vaccination, PCV13 (Synflorix) was listed restricted to use for vaccination of high risk groups. PHARMAC proposes to reinstate the 2011 eligibility criteria for PCV13 restricting its use to the vaccination of high-risk children aged less than 5 years.

Proposed Changes

From 1 July 2017, the following restrictions would apply to the listing of Pneumococcal conjugated (PCV13) vaccine in Section I (National Immunisation Schedule) of the Pharmaceutical Schedule, with equivalent restrictions in DHB Hospitals (deletions shown by strikethrough and additions shown in bold):

**Pneumococcal (PCV13) vaccine**

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 (over the age of 17 months and up to the age of under 18 years) who have previously received four doses of PCV10; or
4. Up to an additional four doses (as appropriate) are funded for high risk children aged under 5 years for (re-)immunisation of patients:
   2.1 on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
   2.2 with primary immune deficiencies; or
   2.3 with HIV infection; or
   2.4 with renal failure, or nephrotic syndrome; or
   2.5 who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
   2.6 with cochlear implants or intracranial shunts; or
   2.7 with cerebrospinal fluid leaks; or
   2.8 receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
   2.9 with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
   2.10 pre term infants, born before 28 weeks gestation; or
   2.11 with cardiac disease, with cyanosis or failure; or
   2.12 with diabetes; or
   2.13 with Down syndrome; or
   2.14 who are pre-or post-splenectomy, or with functional asplenia; or
3. Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients 5 years and over with HIV, for patients pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or
4. 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 is not registered for use over the age of 5 years. It is important that those patients who are considered to be at high risk of pneumococcal disease are able to be vaccinated. The above changes would enable vaccination of patient groups considered to be at high risk and would reinstate the criteria for under 5 year olds that were in place prior to the universal listing of PCV 13 in 2014.
Varicella vaccine

PHARMAC is seeking feedback on proposed amendments to the funding criteria for varicella vaccine (Varilrix). There would be no material change to funded access, the intention is to clarify the criteria.

Proposed Changes

From 1 July 2017, the current restrictions to varicella vaccine [chickenpox vaccine] would be replaced with the following restrictions in Section I (National Immunisation Schedule) of the Pharmaceutical Schedule, with equivalent restrictions applicable in DHB Hospitals (deletions shown by strikethrough and additions shown in bold):

**Varicella vaccine [chickenpox vaccine]**

Either:

1. Maximum of one dose for primary vaccination for either:
   1.1 Children at 15 months: Any infant born on or after 1 April 2016; or
   1.2 For previously unvaccinated children at turning 11 years old on or after 1 July 2017, who have not previously had a varicella infection (chickenpox), or

2. Maximum of two doses for any of the following:
   2.1 Any of the following for non-immune patients:
      2.1.1 with chronic liver disease who may in future be candidates for transplantation; or
      2.1.2 with deteriorating renal function before transplantation; or
      2.1.3 prior to solid organ transplant; or
      2.1.4 prior to any elective immunosuppression*, or
      2.1.5 for post exposure prophylaxis who are immune competent inpatients.; or
   2.2 For patients at least 2 years after bone marrow transplantation, on advice of their specialist, or
   2.3 For patients at least 6 months after completion of chemotherapy, on advice of their specialist, or
   2.4 For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist.
   2.5 For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella, or
   2.6 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, or
   2.7 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
**Haemophilus influenzae type B (Hib) vaccine**

GlaxoSmithKline has notified PHARMAC of a change in pack size for the Hiberix brand as of 1 July 2017, from 10 injections to a single injection per pack. There would be no change to the price per injection. See below, deletions shown by strikethrough and additions shown in bold:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Subsidy</th>
<th>Manufacturer’s price (ex GST)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Haemophilus influenzae type B vaccine</strong></td>
<td>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</td>
<td>Hiberix</td>
<td>49 1</td>
<td>$0.00</td>
<td>$200.00 $20.00</td>
</tr>
</tbody>
</table>

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

**Brand switch transition periods**

PHARMAC previously consulted on and notified of four brand switches involving new listings and Sole Supply Status for GlaxoSmithKline vaccines:
- Pneumococcal (PCV10) vaccine (Synflorix);
- Measles, mumps and rubella vaccine (Priorix);
- *Haemophilus influenzae* type B vaccine (Hiberix); and
- Rotavirus vaccine (Rotarix).

Our decision was that the vaccines will have Sole Supply Status in both the community and DHB hospital settings, with a 0% DV Limit from 1 July 2017 until 30 June 2020.

PHARMAC proposes a change whereby all of GlaxoSmithKline vaccines would have their start date for Sole Supply Status delayed by two months; this would create a transition period. All of the vaccines would still be listed in Part II of Section H and Section I of the Pharmaceutical Schedule from 1 July 2017 (as notified previously).

The four other GlaxoSmithKline vaccines affected by the proposed change in start date are set out below. Please note that these vaccines already have Sole Supply Status, so the impact of the proposed change would be negligible for:
- Varicella vaccine [chicken pox vaccine] (Varilrix)
- Diphtheria, tetanus, pertussis and inactivated polio vaccine (Infanrix IPV);
- Diphtheria, tetanus and pertussis vaccine (Boostrix); and
- Diphtheria, tetanus, pertussis, polio, hepatitis B and *haemophilus influenzae* type B vaccine (Infanrix hexa).

The proposal would result in all of GlaxoSmithKline’s listed vaccines having Sole Supply Status in both the community and DHB hospital settings, with a 0% DV Limit from 1 September 2017 until 30 June 2020.
**Hepatitis A vaccine**

PHARMAC is seeking feedback on a proposal to amend the listing relating to the hepatitis A vaccine, as a result of a provisional agreement with GlaxoSmithKline.

This proposal would result in Havrix/Havrix Junior remaining as the only listed hepatitis A vaccine.

**Details of the proposal**

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

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
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<th>Manufacturer’s price (ex GST)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis A vaccine</td>
<td>Inj 1440 ELISA units in 1 ml syringe</td>
<td>Havrix</td>
<td>1</td>
<td>$0.00</td>
<td>$63.80</td>
</tr>
<tr>
<td>Hepatitis A vaccine</td>
<td>Inj 720 ELISA units in 0.5 ml syringe</td>
<td>Havrix Junior</td>
<td>1</td>
<td>$0.00</td>
<td>$35.00</td>
</tr>
</tbody>
</table>

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

From 1 July 2017 all currently listed strengths of hepatitis A vaccine would be listed, with no change to the current restrictions, in Section I or Part II Section H of the Pharmaceutical Schedule.

Havrix/Havrix Junior would have Sole Supply Status in both the Community and Hospital settings for hepatitis A vaccine from 1 September 2017 until 30 June 2020.

**Background - Current Restrictions**

**Hepatitis A vaccine – Havrix / Havrix Junior**

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.
Hepatitis B recombinant vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the hepatitis B recombinant vaccine, as a result of a provisional agreement with MSD. This proposal would result in HBvaxPRO remaining as the only listed hepatitis B recombinant vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2017 three strengths of HBvaxPRO would remain listed on the National Immunisation Schedule.

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<thead>
<tr>
<th>Chemical</th>
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<th>Manufacturer’s price (ex GST)</th>
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<tbody>
<tr>
<td>hepatitis B recombinant vaccine</td>
<td>Inj 5 mcg per 0.5 ml vial</td>
<td>HBvaxPRO</td>
<td>1</td>
<td>$0.00</td>
<td>$10.00</td>
</tr>
<tr>
<td>hepatitis B recombinant vaccine</td>
<td>Inj 10 mcg per 1 ml vial</td>
<td>HBvaxPRO</td>
<td>1</td>
<td>$0.00</td>
<td>$19.50</td>
</tr>
<tr>
<td>hepatitis B recombinant vaccine</td>
<td>Inj 40 mcg per 1 ml vial</td>
<td>HBvaxPRO</td>
<td>1</td>
<td>$0.00</td>
<td>$40.00</td>
</tr>
</tbody>
</table>

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

From 1 July 2017 all currently listed strengths of hepatitis B recombinant vaccine would be listed with a clarification to the current restrictions in Section I or Part II Section H of the Pharmaceutical Schedule (see below with additions shown in bold).

**Hepatitis B recombinant vaccine – HBvaxPRO (5 mcg & 10 mcg)**

Funded for patients meeting any of the following criteria:
1. for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or
2. for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or
3. for children up to and under 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 non-consensual sexual intercourse; or
7. for patients following immunosuppression; or
8. for solid organ transplant patients; or
9. for post-haematopoietic stem cell transplant (HSCT) patients; or
10. following needle stick injury.

**Hepatitis B recombinant vaccine – HBvaxPRO (40 mcg)**

Funded for any of the following criteria:
1. for dialysis patients; or
2. for 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 2017 until 30 June 2020.
Meningococcal (Groups A, C, Y and W-135) conjugate vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to Meningococcal (Groups A, C, Y and W-135) conjugate vaccine, as a result of a provisional agreement with Sanofi-Aventis.

This proposal would result in Menactra, remaining as the only listed Meningococcal (Groups A, C, Y and W-135) conjugate vaccine.

Details of the proposal

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

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<tr>
<th>Chemical</th>
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<th>Manufacturer's price (ex GST)</th>
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</thead>
<tbody>
<tr>
<td>Meningococcal (Groups A, C, Y and W-135) conjugate vaccine</td>
<td>Inj 4 μg of each meningococcal polysaccharide conjugated to a total of approximately 48 μg of diphtheria toxoid carrier per 0.5 mL dose</td>
<td>Menactra</td>
<td>1</td>
<td>$0.00</td>
<td>$89.95</td>
</tr>
</tbody>
</table>

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

From 1 July 2017 meningococcal (groups A, C, Y and W-135) conjugate vaccine would be listed with no change to the current restrictions in Section I or Part II Section H of the Pharmaceutical Schedule.

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 2017 until 30 June 2020.

Background - Current Restrictions

Meningococcal (groups A, C, Y and W-135) conjugate vaccine – Menactra

Any of the following:

1. Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or

2. One dose for close contacts of meningococcal cases; or

3. A maximum of two doses for bone marrow transplant patients; or

4. A maximum of two doses for patients following immunosuppression*.

Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.

* Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.
Pneumococcal (PPV23) 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 MSD. This proposal would result in Pneumovax 23 remaining as the only listed pneumococcal (PPV23) polysaccharide vaccine.

Details of the proposal

PHARMAC proposes that from 1 July 2017 Pneumovax 23 would remain listed as the pneumococcal (PPV23) polysaccharide vaccine for the National Immunisation Schedule.

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<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
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<th>Subsidy</th>
<th>Manufacturer’s price (ex GST)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal (PPV23) polysaccharide vaccine</td>
<td>Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)</td>
<td>Pneumovax 23</td>
<td>1</td>
<td>$0.00</td>
<td>$40.00</td>
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</table>

From 1 July 2017 the pneumococcal (PPV23) polysaccharide vaccine would be listed with a clarification to the current restrictions in Section I or Part II Section H of the Pharmaceutical Schedule (see below additions shown in bold).

Pneumococcal (PPV23) polysaccharide vaccine – Pneumovax 23

Either:

1. Up to three doses (as appropriate) for patients with HIV, for patients post haematopoietic stem cell transplant, or chemotherapy; pre- or post-splenectomy or with functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or

2. Up to two doses are funded for high risk children to the age of 18 years. for (re-)immunisation of patients:

   2.1 on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
   2.2 with primary immune deficiencies; or
   2.3 with HIV infection; or
   2.4 with renal failure, or nephrotic syndrome; or
   2.5 who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
   2.6 with cochlear implants or intracranial shunts; or
   2.7 with cerebrospinal fluid leaks; or
   2.8 receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
   2.9 with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
   2.10 pre term infants, born before 28 weeks gestation; or
   2.11 with cardiac disease, with cyanosis or failure; or
   2.12 with diabetes; or
   2.13 with Down syndrome; or
   2.14 who are pre-or post-splenectomy, or with functional asplenia.

Pneumovax 23 would have Sole Supply Status in both the Hospital and Community settings for pneumococcal (PPV23) polysaccharide vaccine from 1 July 2017 until 30 June 2020.
Poliomyelitis vaccine

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

This proposal would result in IPOL remaining as the only listed poliomyelitis vaccine.

Details of the proposal

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

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<thead>
<tr>
<th>Chemical</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Poliomyelitis vaccine</td>
<td>Inj 80D antigen units in 0.5 ml syringe</td>
<td>IPOL</td>
<td>1</td>
<td>$0.00</td>
<td>$40.00</td>
</tr>
</tbody>
</table>

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

IPOL would have Sole Supply Status in both the Community and Hospital settings for poliomyelitis vaccine from 1 July 2017 until 30 June 2020.

Background - Current Restrictions

**Poliomyelitis vaccine – IPOL**

Up to three doses for patients meeting either of the following:

1. For partially vaccinated or previously unvaccinated individuals; or
2. For revaccination following immunosuppression.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch-up programmes
**Tuberculin purified protein derivative (Mantoux) test**

PHARMAC is seeking feedback on a proposal to amend the listing relating to tuberculin purified protein derivative (Mantoux) test, as a result of a provisional agreement with Sanofi-Aventis.

This proposal would result in Tubersol being the only listed tuberculin purified protein derivative (Mantoux) test.

*Details of the proposal*

PHARMAC proposes that from 1 July 2017 Tubersol would be listed on the Pharmaceutical Schedule with no restrictions.

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<tr>
<th>Chemical</th>
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<th>Manufacturer’s price (ex GST)</th>
</tr>
</thead>
<tbody>
<tr>
<td>tuberculin purified protein derivative (Mantoux) test</td>
<td>Inj 5 TU per 0.1 ml, 1 ml vial</td>
<td>Tubersol</td>
<td>1</td>
<td>$0.00</td>
<td>$50.00</td>
</tr>
</tbody>
</table>

Tubersol would have Sole Supply Status in both the Community and Hospital settings for tuberculin purified protein derivative (Mantoux) test, from 1 July 2017 until 30 June 2020.

*Background*

Tuberculin purified protein derivative (Mantoux) test is currently listed without a brand in Part II of Section H of the Pharmaceutical Schedule. This is the first time that a provisional agreement has been reached for the test and would result in the Tubersol brand being listed in Section B and Part II of Section H of the Pharmaceutical Schedule.
Background to this consultation

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 in 2016, in 2015 PHARMAC asked 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 Immunisation Subcommittee minutes are available on our website.

On 15 February 2016 PHARMAC released an RFP for the supply of various vaccines.

Following receipt of proposals, PHARMAC sought further clinical advice from the Immunisation Subcommittee, at the May and November 2016 meetings, regarding refinement of the eligibility criteria for several vaccines.

PHARMAC has previously consulted on and notified of decisions relating a number of vaccines resulting from the 2016 RFP. The proposed listings and amendments to the National Immunisation Schedule in this consultation would wrap up the majority of the remaining outstanding items from the 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 with the “Xpharm" restriction with a $0.00 subsidy. An Xpharm listing means that pharmacies cannot claim subsidy because PHARMAC has made alternative distribution arrangements.