CONSULTATION

PHARMAC
Pharmaceutical Management Agency

**19 December 2013**

# Proposal to amend listings in the National Immunisation Schedule

PHARMAC is seeking feedback on proposals relating to the supply of vaccines for the New Zealand National Immunisation Schedule.

## Proposed Changes:

- The current Bacillus Calmette-Guerin vaccine (BCG) vaccine supplied by Sanofi-Aventis would be replaced by the Bacillus Calmette-Guerin vaccine (BCG) supplied by bioCSL

- Access to the diphtheria, tetanus, acellular pertussis, inactivated polio, *Haemophilus influenzae type B* and hepatitis B vaccine and the *Haemophilus influenzae type B* vaccine would be widened to include re-immunisation following immunosuppression

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

- bioCSL
  - Bacillus Calmette-Guerin vaccine (BCG)

- GlaxoSmithKline
  - diphtheria, tetanus, acellular pertussis, inactivated polio, *Haemophilus influenzae type B* and hepatitis B vaccine (Infanrix Hexa)

- Sanofi Aventis
  - *Haemophilus influenzae type B* vaccine

All contracted vaccines would have Sole Subsidised Supply and Hospital Supply Status, making them the only vaccines of these kind funded the community and available in hospitals.

## Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **4 pm Friday, 24 January 2014** to:


Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: vaccines@pharmac.govt.nz

Fax: 04 460 4995


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.




Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

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**

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 would remain the same as currently. 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. As noted in the following pages, PHARMAC has negotiated a lower net purchase price for the vaccines that are the subject of this consultation; however these net prices are confidential.

The restrictions applying to all vaccines in Section I would be amended to describe the number of doses that would be funded rather than a 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 members of 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 Immunisation Subcommittee minutes are linked below.

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

## 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 NZ Ltd.

In summary, this proposal would result in the hexavalent vaccine, Infanrix-Hexa, being the only listed hexavalent vaccine.

**Details of the proposal**

*Infanrix-Hexa*

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

Infanrix-Hexa 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, 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 inj 10 mcg haemophilus influenza type B vaccine | Infanrix-Hexa | 10 | $0.00 | $1,300.00 |

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

**Proposed changes:**

From 1 July 2014 the current restrictions applying to the hexavalent 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 patients meeting the following criteria

1. Up to four doses for children up to the age of 7 for primary immunisation

2. Up to four doses (as appropriate) for children are funded for (re-)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; renal dialysis and other severely immunosuppressive regimens

3. Up to five doses for children up to the age of 7 receiving 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 the appropriate schedule for catch up programmes.

Infanrix-Hexa would have sole supply status in both the community and hospital settings for the hexavalent vaccine from 1 July 2014 until 30 June 2017.

**Background**

The Immunisation Subcommittee reviewed the hexavalent vaccine at its April 2013 meeting and advised:

> The Subcommittee recommended the following restrictions be applied to diphtheria, tetanus pertussis-containing vaccines (as DTaP-IPV or DTaP-IPVHepB/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 **recommended** that all vaccines discussed in the General review should include an allowance for revaccination of up to the entire number of vaccines for patients who have undergone HSCT, solid organ transplant or chemotherapy, with a high priority. The Subcommittee considered that a restriction broadly along the following lines for each vaccine would be appropriate:
>
> An additional xx doses (as appropriate) are funded for (re-)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; pre- or post- solid organ transplant, renal dialysis and other severely immunosuppressive regimens

## Bacillus Calmette-Guerin vaccine

PHARMAC is seeking feedback on a proposal to amend the listing relating to the diphtheria, Bacillus Calmette-Guerin vaccine (BCG) as a result of a provisional agreement with bioCSL.

This proposal would result in the BCG vaccine being the only listed BCG vaccine.

**Details of the proposal**

*BCG vaccine*

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

BCG 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 | Manufacture's price (excl GST) |
|---|---|---|---|---|---|
| Bacillus Calmette-Guerin vaccine | Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, 2-8 x 105 cfu powder and solvent for suspension for injection | BCG Vaccine | 10 | $0.00 | $999.50 |

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

The currently funded Sanofi BCG vaccine would be delisted from 30 September 2014.

**Proposed change**

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

> For infants at increased risk of tuberculosis
> Note: increased risk is defined as:
> 1. Living in a house or family with a person with current or past history of TB; or
> 2. Having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer; or
> 3. During their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000.
>
> Note: a list of countries with high rates of TB are available at http://www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/tuberculosis?qt-moh_topic_sheet_tabs=3_qt-moh_topic_sheet_tabs or www.bcgatlas.org/index.php

bioCSL's BCG vaccine would have sole supply status in both the community and hospital settings from 1 October 2014 until 30 June 2017.

## 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 Sanofi-Aventis New Zealand Limited.

This proposal would result in haemophilus influenzae type B vaccine, Act-HIB, being the only listed haemophilus influenzae type B vaccine.

**Details of the proposal**

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

Act-HIB 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) |
|---|---|---|---|---|---|
| *Haemophilus influenzae* type B vaccine | 10 mcg vial with diluent syringe | Act-HIB | 1 | $0.00 | $11.90 |

PHARMAC has negotiated a lower net purchase price for Act-HIB, however this net price is confidential.

**Proposed changes**

From 1 July 2014 the current restriction applying to haemophilus influenzae type 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:

> One dose for patients meeting any of the following:
>
> 1. For primary vaccination in children; or
> 2. For revaccination of children following immunosuppression; or
> 3. For children aged 0-18 years with functional asplenia; or
> 4. For patients pre- and post-splenectomy; or
> 5. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Act-HIB would have sole supply status in both the community and hospital settings for haemophilus influenzae type 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. It advised:

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

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