

10 March 2014

## Changes to the National Immunisation Schedule

PHARMAC is pleased to announce further decisions related to the National Immunisation Schedule (NIS) that will take effect from 1 July 2014. This was the subject of a consultation letter dated 19 December 2014, which can be found at the following link: <http://www.pharmac.health.nz/news/consultation-2013-12-19-nis-2/>.

The decisions mean that from 1 July 2014:

- The currently funded Bacillus Calmette-Guerin vaccine (BCG) will continue to be supplied through an agreement with bioCSL;
- Funded access to the diphtheria, tetanus, acellular pertussis, inactivated polio, haemophilus influenzae type B and hepatitis B vaccine and also to the haemophilus influenzae type B vaccine will be widened to include re-immunisation following immunosuppression; and
- The restriction applying to funding for the diphtheria, tetanus, acellular pertussis and inactivated polio vaccine will be amended to allow catch up programs to the age of 10 years.

All the vaccines will continue to be centrally purchased by PHARMAC's nominated agent (currently the Institute of Environmental Science and Research Limited) and distributed directly to vaccinators at no cost.

Details of the decisions are set out on the following pages.

### Responses to consultation

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 4pm on Friday 24 January 2014 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal.

Themes raised in the responses, and PHARMAC commentary on those themes, are included at the end of this notification.

## **Details of the decision**

### **Infanrix-hexa**

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

<b>Chemical</b>	<b>Presentation</b>	<b>Brand</b>	<b>Pack size</b>	<b>Subsidy</b>
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 haemagglutinin, 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

From 1 July 2014 the hexavalent vaccine will be available for eligible patients meeting the following criteria in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule):

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

## **BCG vaccine**

From 1 July 2014 BCG vaccine will be listed on the National Immunisation Schedule.

<b>Chemical</b>	<b>Presentation</b>	<b>Brand</b>	<b>Pack size</b>	<b>Subsidy</b>
Bacillus Calmette-Guerin vaccine	Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, 2-8 x 10 <sup>5</sup> cfu vial with diluent	BCG Vaccine	10	\$0.00

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

From 1 July 2014 the BCG vaccine will be available for eligible patients meeting the following criteria in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule):

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 is 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](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](http://www.bcgatlas.org/index.php)

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

## **Haemophilus influenzae type B vaccine**

Haemophilus influenzae type B vaccine, Act-HIB, will remain the only listed vaccine for *Haemophilus influenzae* type B.

Act-HIB will continue to be centrally purchased by PHARMAC's nominated agent (the Institute of Environmental Science and Research Limited) and distributed directly to vaccinators at no cost.

<b>Chemical</b>	<b>Presentation</b>	<b>Brand</b>	<b>Pack size</b>	<b>Subsidy</b>
<i>Haemophilus influenzae</i> type B vaccine	Inj 10 mcg vial with diluent syringe	Act-HIB	1	\$0.00

From 1 July 2014 the haemophilus influenzae type B vaccine will be available for eligible patients meeting the following criteria in Section H (the Hospital Medicines List) and Section I (National Immunisation Schedule):

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 will 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.

### ***Diphtheria, tetanus, acellular pertussis and inactivated polio vaccine***

From 1 July 2014 the restrictions applying to DTaP-IPV in Section H (the Hospital Medicines List) and in Section I (National Immunisation Schedule) will be amended as follows (deletions in strikethrough, additions in bold):

Funded for any of the following

1. A single dose for children up to the age of 7 who have completed primary immunisation; or
2. A course of up-to four vaccines is funded for catch up programmes for children (to the age of ~~7~~**10** 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.

### **Feedback received**

As noted earlier, we appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 24 January 2014 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

<b>Theme</b>	<b>PHARMAC staff response</b>
Supports the change of the BCG vaccine to the Serum Staten Institute BCG vaccine due to issues with adverse events.	Noted
Support the proposals.	Noted

Theme	PHARMAC staff response
<p data-bbox="177 226 815 293">Request accessibility of the hexavalent Infanrix vaccine up to age 10 years (not 7 years).</p> <p data-bbox="177 383 815 472">Request <i>Haemophilus influenzae</i> type B vaccine (HiB) to be available as a catch up for HIV patients aged 5-18 years</p>	<p data-bbox="815 226 1410 416">PHARMAC sought the advice of the Immunisation Subcommittee at its February 2014 meeting regarding re-immunisation with the hexavalent vaccine up to the age of 10 years. The minutes from this meeting are not yet available.</p> <p data-bbox="815 439 1410 589">PHARMAC sought the advice of the Immunisation Subcommittee at its February 2014 meeting regarding the need for the HiB vaccine for HIV patients aged 5-18 years. The minutes from this meeting are not yet available.</p>

### More information

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