Consultation

PHARMAC
TE PĀTAKA WHAIORANGA

Proposal to widen access to pertussis (whooping cough) vaccine

14 May 2019

What we're proposing

PHARMAC is seeking feedback on a proposal to widen access to funded pertussis (whooping cough) vaccine for all pregnant women at any time during their pregnancy, as well as for parents of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days.

This would be achieved by widening access to the diphtheria, tetanus and pertussis vaccine (DTaP; funded brand name Boostrix) in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2019.

Consultation closes at **5 pm on Tuesday, 4 June 2019** and feedback can be emailed to consult@pharmac.govt.nz.

What would the effect be?

Currently, vaccination against pertussis is funded for pregnant women who are between 28 to 38 weeks gestation. It is proposed that from 1 July 2019, all pregnant women would be eligible to receive the vaccination at any point during their pregnancy. Vaccination against pertussis during pregnancy is important because maternal antibodies to pertussis give protection to premature and full-term infants before they can receive their first vaccination at 6 weeks of age.

From 1 July 2019, parents of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days would be eligible to receive vaccination against pertussis to reduce the risk of introducing pertussis to these units when they visit their child. Eligible parents would need to visit their general practitioner to receive this vaccine.

Who we think will be interested

- doctors in general practice, nurses, vaccinators and midwives
- paediatricians, DHBs, hospital pharmacists
- suppliers and wholesalers
- organisations with an interest in immunisation

About pertussis and the vaccine

Pertussis (also called whooping cough) is a highly infectious bacterial disease that is spread by coughing and sneezing. Pertussis can be very serious for infants and young children. If young children catch pertussis, they may have difficulty feeding or breathing, may need to be hospitalised and may have serious complications such as pneumonia and brain damage.

Pertussis vaccine is given as a single injection of a mixture that that includes three vaccines: diphtheria, tetanus and pertussis (DTaP; funded brand name Boostrix). Boostrix is used for the immunisation of children and adults against these three diseases. Boostrix is also approved for use as a booster vaccination in people aged four years and older. Each 0.5 ml dose contains diphtheria toxoid, tetanus toxoid and *Bordetella pertussis* antigens.

Immunity to pertussis develops within 10 to 14 days of receiving the vaccine, but the effectiveness of the vaccine lessens over time so it is recommended that pregnant women should receive a booster, even if they were fully immunised as a child.

Pregnant women who get a pertussis vaccine booster can pass on their immunity to their unborn child, providing protection to the child until it is old enough to receive its first vaccination. This is important for the protection of premature and full-term infants. Even if a woman has received a pertussis vaccine booster during a previous pregnancy, another booster would be required during each subsequent pregnancy to provide protection for each child.

Why we're proposing this

Pertussis is very contagious and easily passed from person to person by coughing and sneezing. New Zealand is currently experiencing a national pertussis outbreak, with infants and children being most at risk.

Pertussis-containing vaccine is currently funded for pregnant women from 28 to 38 weeks gestation, so that maternal antibodies can pass to the unborn child providing it with protection against pertussis from birth until its own vaccination at 6 weeks of age.

We received a funding application for the vaccination of the parents of premature children admitted to a Neonatal Intensive Care Unit (NICU) or Specialist Care Baby Unit (SCBU). The Immunisation Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) recommended widening of access to pertussis vaccine initially starting with parents only of either all infants born at 28 weeks or less and/or of infants admitted to NICU or SCBU for a minimum stay of 3 days who had not been exposed to maternal vaccination at least 14 days prior to birth, with a high priority. This recommendation was accepted by PTAC. More information, including links to relevant clinical advice, can be found on the Application Tracker.

We also received clinical advice from the Immunisation Subcommittee that infants born prematurely before 28 weeks gestation are also at risk of pertussis infection if the mother has not been vaccinated against pertussis at least 14 days before the birth. The Subcommittee recommended that access to maternal pertussis vaccination be widened to include women in their second trimester of pregnancy with a high priority and this recommendation was accepted by PTAC.

More information about this, including links to the relevant clinical advice, can be found on the Application Tracker.

The Immunisation Subcommittee also advised us that vaccinating parents of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for at least 3 days would reduce the risk of parents introducing pertussis to these units when they visit their child.

This proposal is in line with the clinical advice we have received.

Details about our proposal

We are proposing to widen access to the DTaP vaccine in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2019 for pregnant women at any gestational stage and also to parents of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for at least 3 days.

The eligibility criteria for the DTaP vaccine (Boostrix) would be amended in Section I and Part II of Section H of the Pharmaceutical Schedule as follows (amendments in bold, deletions in strikethrough).

Section I

Funded for any of the following criteria:

1. A single **dose** ~~vaccine~~ for pregnant **women** ~~woman between gestational weeks 28 and 38~~ **at any gestational stage of each pregnancy**; or
2. **A single dose for parents of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days, who had not been exposed to maternal vaccination at least 14 days prior to birth; or**
3. A course of up to four **doses** ~~vaccines~~ is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or
4. 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.

Section H

Restricted
Initiation
Any of the following:

1. A single **dose** ~~vaccine~~ for pregnant **women** ~~woman between gestational weeks 28 and 38~~ **at any gestational stage of each pregnancy**; or
2. **A single dose for parents of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days who had not been exposed to maternal vaccination at least 14 days prior to birth; or**
3. A course of up to four **doses** ~~vaccines~~ is funded for children from age 7 up the age of 18 years inclusive to complete full primary immunisation; or
4. 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.

Please note that on 9 May 2019 we issued a consultation that includes a proposal to amend the eligibility criteria, from 1 July 2020, for the DTaP vaccine (Boostrix) to include the people for whom adult diptheria and tetanus vaccine (brand name ADT Booster) is currently funded and to make some other changes to the criteria. If both proposals are approved, both sets of eligibility criteria would be merged.

To provide feedback

Send us an email: consult@pharmac.govt.nz by **4 June 2019**.

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.