NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

12 December 2012

Decision to amend the diphtheria, pertussis and tetanus vaccine (Boostrix) listing

PHARMAC is pleased to announce the approval of a proposal to amend the criteria for accessing funding for the combination diphtheria, pertussis and tetanus vaccine (under the brand name Boostrix) from 1 January 2013.

The consultation document in relation to the proposal can be found at http://pharmac.govt.nz/2012/11/14/Consultation%20on%20widening%20access%20to%20pertussis%20to%20pregnant%20women.pdf

Details of the Decision

The restriction applying to Boostrix vaccine in Section I of the Pharmaceutical Schedule will be amended from 1 January 2013 as follows (additions in **Bold**):

> For children aged 11 years old**, and pregnant women between gestational weeks 28 and 38 during epidemics**

The decision on whether there is an epidemic will be made by PHARMAC, following consultation with the Ministry of Health and the Immunisation Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC). This will be notified to treating clinicians and published on PHARMAC's website.

For the avoidance of doubt, there is currently a pertussis epidemic; therefore, from 1 January 2013 Boostrix will be available to pregnant women between gestational weeks 28 and 38.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 29 November 2012 were considered in their entirety in making a decision on the proposed changes.

Most responses were supportive of the proposal, and the following page sets out the issues raised in relation to specific aspects of the 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

Theme	PHARMAC Comment
Recommend widening the age range from 28 gestational weeks up until 2 weeks post-delivery (i.e. not stopping at 38 gestational weeks).	At this time we are not proposing to extend the vaccine postpartum. Evidence suggests that it takes two weeks to develop antibodies to the vaccine and this would result in the newborn being exposed for up to two weeks, significantly reducing the benefit to the infant of vaccinating the mother. We will seek further advice from the Immunisation Subcommittee of PTAC at its February 2013 meeting to assess whether there may be additional benefit in vaccinating the mother in these situations.
Recommend this vaccination be available permanently to pregnant women and not just when an outbreak is identified. or Recommend that widen access outside of epidemics to include when the pregnant woman is a contact of a probable or confirmed pertussis case.	Given the potential risks associated with vaccination during pregnancy PHARMAC considers that extending the vaccine indefinitely is not appropriate at this time. We will seek further advice from the Immunisation Subcommittee of PTAC at its February 2013 meeting to assess whether there may be additional benefit in vaccinating a wider group of people both during and outbreak, and after an outbreak has subsided.
If offering this vaccine routinely in the last trimester of pregnancy is not possible, then access to the vaccine once an outbreak is identified should be implemented at a regional level (i.e. Northern, Midland, Central, South Island) not on a DHB by DHB basis.	PHARMAC is considering how to manage localised outbreaks, and are considering how to define local outbreaks. We will be seeking the advice of the Immunisation Subcommittee of PTAC at its February 2013 meeting and will ensure this suggestion is considered. As we are currently in an epidemic situation the vaccine will be funded from 1 January 2013 in all areas.
The vaccine should also be funded for lead maternity carers and other health care personnel working with neonates and young infants	We consider that this is an occupational health issue and the responsibility of employers.
Clear consumer information regarding the effect of the vaccine and the evidence base that supports its use is required for informed consent to be given.	PHARMAC will be working with the Ministry of Health regarding the preparation of information for consumers.
Is the immunisation fee for the General Practice consultation, which will be required for the woman to receive a vaccine, funded also?	Yes, the immunisation benefit will be available for providing this vaccine to pregnant women meeting the criteria.

Theme	PHARMAC Comment
Given the theoretical risk that "the passive immunity" the infant receives would impact on the long term efficacy of the childhood pertussis vaccination and it is possible that more conclusive information will be available shortly to determine whether this theoretical risk has any basis, it would seem prudent to await these results before deciding to fund the vaccine for pregnant women.	The results of a study investigating this issue are anticipated in the next few months; these may not be conclusive and we consider delaying this decision would delay a potential benefit to infants who are most at risk of morbidity and mortality from pertussis. We consider there is sufficient evidence to make funding available; however we note that the risks and benefits need to be made clear to enable patients to give informed consent. We will continue to analyse the available evidence, and we would reconsider this funding decision if necessary. We will also ensure any new information is made available to health professionals.

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.