

5 May 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202204813

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 30 March 2022 for information regarding paediatric vaccines and vaccination during pregnancy. I will respond to each part of your request in turn.

*Pediatric Questions relating to vaccines:
For the Diphtheria/Tetanus/Pertussis/Polio vaccine what was the reason for bringing the scheduled date of vaccine forward for children?*

The Diphtheria/Tetanus/Pertussis/Polio vaccine (DTaP-IPV, also known as Infanrix-IPV) is given at 4 years of age. There is also a different combination vaccine 'Diphtheria/ Tetanus/Pertussis/ HepB and Hib vaccine (DTaP-IPV-HepB/Hib, also known as Infanrix-hexa) which is given at 6 weeks, 3 months and 5 months of age. The timing of both DTaP-IPV and DTaP-IPV-HepB/Hib vaccines has not changed since these vaccines commenced in June 2008.

How long does the immunity last for this booster? Can you please link the clinical proof / research and or evidence of this? I am reading in the booklet - can you please confirm that the below is correct?

*Pediatric Use
Safety and effectiveness of INFANRIX in infants younger than 6 weeks of age and children 7 to 16 years of age have not been established. INFANRIX is not approved for use in these age? Is this the most up to date information? Please provide link as to research and approval documents in relation to the age bracket 7 weeks to 6 years. Please send most up to date link or PDF copy.*

Of two vaccines noted above, (Infanrix-Hexa and Infanrix-IPV), only the Infanrix -IPV is a booster. The other three doses of Infanrix-Hexa are primary doses and do not require boosters.

You may be interested in the following datasheets on safety information of the above vaccines:

- www.medsafe.govt.nz/Profs/Datasheet/I/Infanrixhexainj.pdf.
- www.medsafe.govt.nz/consumers/cmi/i/infanrixipv.pdf.

The World Health Organization recommends six doses of a tetanus containing vaccine should be given in a lifetime. Further information can be found here: www.who.int/health-topics/tetanus#tab=tab_3.

The New Zealand Immunisation Schedule has vaccines containing Tetanus, Diphtheria and Pertussis given at six weeks, three months, five months, four years, 11 years, and 65 years old. There is more information at: www.health.govt.nz/our-work/immunisation-handbook-2020/4-immunisation-special-groups.

Pertussis

Pertussis (whooping cough) is a disease of the respiratory tract caused by B. pertussis. The role of the different components produced by B. pertussis in either the pathogenesis of, or the immunity to, pertussis is not well understood. There is no well established serological correlate of protection for pertussis? Is this the most up to date information?

Section 4.1 of the Immunisation Handbook provides the latest information on the recommended pertussis, influenza and COVID-19 vaccinations for pregnant women. The relevant studies and evidence are references in the section and listed at the end of the chapter:
www.health.govt.nz/our-work/immunisation-handbook-2020/4-immunisation-special-groups#4-1.

INFANRIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility? Is this the most up to date information?

On 19 April 2022, the Ministry contacted you via email requesting for you to clarify what specific vaccines you were referring to. However, it appears this statement has been lifted from the packaging slip approved by the Food and Drug Administration (FDA) for the use of the Infranrix vaccine in the United States. For many routine vaccines approved for use by the FDA, including MMR (measles, mumps and rubella), section 13 states that the vaccine “has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.” This statement of fact merely means that there was no need for further testing because toxicology studies conducted at the preclinical phase showed no signs of adverse effects from the vaccine or its individual components.

Are you able to take a test to check for current immunity of Diphtheria/Tetanus/Pertussis/Polio vaccine in New Zealand? If so please link information of how and cost.

Serology can be used to assess the immunity status against diphtheria and tetanus and is particularly used with immunocompromised patients. It could be also used to assess immunity against polio, though this requires the availability of serologic test against the three types of poliovirus.

However, serology is not considered to be a reliable indicator for a patient's immune status against pertussis and should not be used in this context. For cost and availability, you will need to contact the laboratory service.

Please provide evidence of the studies and research completed in regards to why providing these vaccines altogether at once for multiple issues is safe. Please send most up to date link or PDF copy.

Are you able to test for immunity for any other vaccines post administration on the schedule at any time also in New Zealand? If so please link information of how and cost. Please list any legal cases relating to the above vaccine due to adverse reactions - both in New Zealand and globally. Please send most up to date link or PDF copy.

Please refer to the Immunisation Handbook for further information. The Immunisation Handbook is available here: www.health.govt.nz/our-work/immunisation-handbook-2020

Pregnancy Questions relating to vaccines:

Is there any research or information available on any long term side effects (on both woman and child) of pregnant woman taking the Influenza and the Whooping cough (pertussis) vaccine? Please link the research or any studies that have been completed and the results of those. Please ensure these are the most up to date links. Please send most up to date link or PDF copy.

Regrading adverse reaction please list those in table format, in date and age order - in full - via email. Please send most up to date link or PDF copy.

Please list any legal cases relating to the above vaccine due to adverse reactions - both in New Zealand and globally. Please send most up to date link or PDF copy.

Section 4.1 of the Immunisation Handbook provides the latest information on the recommended Pertussis, Influenza and COVID-19 vaccinations for pregnant women. The relevant studies and evidence are references in the section and listed at the end of the chapter.

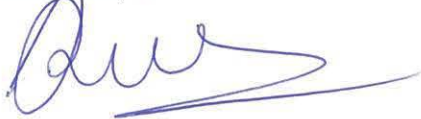
www.health.govt.nz/our-work/immunisation-handbook-2020/4-immunisation-special-groups#4-1.

Data on adverse reactions to vaccines is held by Centre for Adverse Reactions Monitoring and can be accessed here www.medsafe.govt.nz/Projects/B1/ADRDisclaimer.asp

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases

Nāku noa, nā



Astrid Koornneef

Director

National Immunisation Programme