

29 April 2022

s 9(2)(a)

By email: **s 9(2)(a)**
Ref: H202204804

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 vaccines. Please note if you have any questions or concerns about vaccinations, please discuss this with your health provider.

You may be interested that the *Immunisation Handbook* provides clinical guidelines for health professionals on the safest and most effective use of vaccines in their practice. These guidelines are based on the best scientific evidence available at the time of publication, from published and unpublished literature: www.health.govt.nz/publication/immunisation-handbook-2020.

On 19 April 2022, the Ministry contacted you requesting that you clarify what sites or sources of information you were referring to. As we have not received a reply from you to date, the Ministry has answered with the information presented. Please find the answers to each part of your request below.

I am reading on the site that - There is no increased risk of reactions to the vaccine for Influenza and Whooping Cough in pregnant women or their unborn babies. Can you please send me the links or PDF copy of the research and clinical trials that were completed to establish this statement?

Afluria Quad is the funded vaccine to help prevent influenza in New Zealand. Influenza immunisation is recommended and free for those who are pregnant at any stage of pregnancy. Information about the vaccine and use in pregnancy and during lactation can be found here: www.medsafe.govt.nz/profs/Datasheet/a/Afluriainj.pdf.

Boostrix-IPVI am reading - does this mean it has not been trialled with the Influenza vaccine? So there are no trials post birth to follow any adverse reactions or long-term vaccine injuries? Fertility - also there is no data as to whether this affects the fertility of the mother or child long-term?

The funded whooping cough vaccine in pregnancy is Boostrix which can be used during the second or third trimester of pregnancy in accordance with official recommendations. The datasheet for Boostrix can be found here: www.medsafe.govt.nz/Profs/Datasheet/b/Boostrixinj.pdf.

Has there been any follow up research completed regarding children having any adverse reactions post pregnancy to either of these vaccines given? Am I correct that there has

been zero post marketing surveillance? Is there any known recorded adverse reactions both Nationally and Globally to these vaccines for children post birth?

Medsafe contracts the Centre for Adverse Reactions Monitoring (CARM) at the University of Otago to collect spontaneous reports of suspected adverse reactions to all medicines in use in New Zealand including vaccines – you can see the results in this database here: www.medsafe.govt.nz/Projects/B1/ADRDisclaimer.asp.

It says - does this mean that authorisation has expired? How long does this authorisation last?

Date of first authorisation/renewal of the authorisation

Date of first authorisation: 6 July 2005

Date of last renewal: 16 December 2008

The information you are quoting is not relevant to New Zealand. You can find the product information for New Zealand medicines here: <https://www.medsafe.govt.nz/Medicines/infoSearch.asp>.

Where is the link to the Influenza vaccine used during pregnancy re: brand?

<https://www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/influenza>

The brand of influenza vaccine is subject to change each year. In 2022, all brands of influenza vaccine, except for Fluad Quad (an adjuvanted vaccine only approved for people aged 65 and older), are recommended for people at all stages of pregnancy.

What is the definition of vaccine? Are these classified as vaccines or boosters?"

Legal definitions are contained in legislation and in the instance of a definition of a vaccine this would be in the Medicines Act 1981.

The United States Centers for Disease Control and Prevention (CDC) defines a vaccine as a preparation that is used to stimulate the body's immune response against diseases¹.

A booster dose is an extra administration of vaccine after an earlier (primer) dose.

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**

¹ CDC definition of terms: www.cdc.gov/vaccines/vac-gen/imz-basics.htm