

16 July 2021

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202107632

Dear 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 23 June 2021.

Each part of your request is responded to below.

*1/ Is Medsafe aware the CDC is holding an emergency meeting this week on the risk of myocarditis for young people vaccinated with mRNA Covid-19 vaccines?
(If so when were you made aware of this?).*

Medsafe was advised of the emerging safety signal of myocarditis for young people vaccinated with the mRNA COVID-19 vaccines by the Food and Drug Administration (FDA) on 18 May 2021.

*2/ Is Medsafe aware the current advice from The WHO posted on their website is that children under 18 should not be vaccinated against Covid-19 due to not enough data and the low risk to children from Covid-19?
3/ What data does Medsafe hold that The WHO doesn't to come to a polar opposite conclusion where you now have granted provisional use?
(What long term safety, peer review study and any other empirical evidence did you base that decision on?).*

The World Health Organization (WHO) has updated its advice relating to the vaccination of children under 18. The updated advice can be found at:

www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/advice

4/ How many children under the age of 18 have already been vaccinated for covid-19 in NZ?

The information you have requested is provided in the table below:

Age at First Vaccination	First Dose Received	Second Dose Received	Number of People
17	Yes	Yes	1098
17	Yes	No	619
16	Yes	Yes	949
16	Yes	No	506

As of 25 June 2021, the Ministry's COVID-19 Vaccination and Immunisation Programme has been advised that 14 people under the age of 16 years have received the Pfizer COVID-19 vaccine. Of these, 12 have received one dose of the vaccine and two have received two doses.

5/ Did Medsafe have any involvement in the cancelling of the Hydroxychloroquine trial here in NZ last year? (If so who? Name and position of who made that decision).

Medsafe did not have any involvement in the decision to cancel any hydroxychloroquine trial.

6/ Does Medsafe receive any other funding apart from government?

7/ Does Medsafe receive any funding via proxy or directly from pharmaceutical companies?

In accordance with the Medicines Act 1981 and the Misuse of Drugs Act 1975, Medsafe charges fees for a range of applications for approval and licenses for a range of activities. Information on the activities subject to fees are described in the Medicines Act 1981 and the Misuse of Drugs Act 1975. Information about the fees can be found here: www.medsafe.govt.nz/regulatory/fees.asp

8/ Does Medsafe receive funding from any social network or internet services like google, Facebook etc?

Medsafe does not receive funding from any social network or internet services.

9/ Full names and positions at Medsafe of the staff who made the decision and signed off for use of the Pfizer vaccine in children for Covid-19.

As Group Manager Medsafe, Chris James recommended that provisional consent be given under section 23 to enable adolescents aged between 12 and 16 to receive the Pfizer Comirnaty vaccine.

Please note, the COVID-19 vaccine is not currently approved by Cabinet for use for those under the age of 16 and at present there is no specific COVID-19 vaccine information for this age group. While the use of vaccine for age 12-15 is approved by Medsafe, Cabinet approval for the COVID-19 Vaccination and Immunisation Programme (CVIP) rollout in this age cohort is required.

The Notice regarding provisional consent to the distribution of the Pfizer vaccine is publicly available at: www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette-Jun-2021.pdf. There is more information about the vaccine approval process at: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.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/responses-official-information-act-requests.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Derek Fitzgerald', written in a cursive style.

Derek Fitzgerald
Acting Group Manager
Medsafe