

6 October 2021

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

By email:

Ref: H202113070

Dear

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 23 September 2021. I shall respond to each part of your request below:

Do you provide the pfizer fact sheet to 12-15 year olds who have made an appointment (and in fact all people making an appointment)? Consumer Medicine Information 2020 Template (medsafe.govt.nz)

Anyone receiving a vaccine is provided with the following document: https://covid19.govt.nz/assets/resources/vaccine-resources/COVID-19-vaccine_What-to-expect.pdf.

Further vaccine fact sheets can be found here: https://covid19.govt.nz/covid-19-vaccines/get-the-facts-about-covid-19-vaccine-fact-sheets/.

have the 58 questions from medsafe been answered? please send me the answers to those questions.

The status of the obligations is publicly available at: www.medsafe.govt.nz/COVID-19/status-of-applications.asp.

Any further information is withheld under section 9(2)(b)(ii) of the Act, where its release would likely unreasonably prejudice the commercial position of the person who supplied the information.

what dose is given to a child is it based on weight and age? how has the correct dosage for a child been determined?

Approved dosing information can be found in the datasheet which is publicly available here: hwww.medsafe.govt.nz/profs/Datasheet/c/comirnatyini.pdf

what are the effects of the vaccine on puberty hormones? I expect you to reference actual studies done of the pfizer vaccine.
what long terms affects on fertility have been studied? show actual data

The Ministry of Health (the Ministry) does not hold any information regarding this as it is not a research organisation. Please note, the Ministry does not conduct studies or research. A range of peer reviewed scientific research about the COVID-19 virus has been published on *PubMed* by the National Center for Biotechnology Information at the National Institutes of Health in the United States at: https://pubmed.ncbi.nlm.nih.gov and www.ncbi.nlm.nih.gov/sars-cov-2.

how many 12-15 year olds were in the pfizer trial? how many and what kind of side effects did the children in the trial have? how are those children doing NOW? You need to quote reputable information.

This information can be found here: https://www.nejm.org/doi/full/10.1056/NEJMoa2107456.

what is the actual statistical risk of myocarditis and pericarditis? Actual reputable studies need to be referenced? How does this compare to the background rate for the 12-15 age group

This information can be found here: https://www.nejm.org/doi/full/10.1056/NEJMoa2110475.

what is the severity of myocarditis and pericarditis when it occurs and what is the treatment plan and what are the long term prognosis?

The Ministry is unable to provide clinical advice. This is determined by individual clinical assessment conducted by doctors. The Immunisation Advisory Centre at the University of Auckland, which has been contracted by the Ministry to undertake vaccinator training, has published information for health professionals which is available at: https://covid.immune.org.nz/resources/written/myocarditis-and-mrna-covid-19-vaccine-new-zealand-information-health.

what is the covid 19 death rate for 12-15 years?

Case demographics can be found at the following link: https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-current-cases.

what is the vaccine death rate for 12-15 year olds? world wide - look at vaers, the yellow card system, carm in NZ and all others and remember that that reporting is only 1-10% of actual - an answer with actual references.

I have interpreted this question as the deaths of 12-15 year olds from any vaccine. New Zealand data is summarised in the weekly AEFI report mortality data is here https://minhealthnz.shinyapps.io/mortality-web-tool/. The Ministry does not hold worldwide data.

what is the actual case rate for 12-15 year olds of the disease and I don't mean a positive PCR test I mean real cases i.e., children with disease symptoms?

Age in years	Asymptomatic	Symptomatic
12	14	37
13	9	39
14	10	49
15	3	37
Total	36	162

To 1 October 2021, 108 cases in the current outbreak are aged between 12-15, more demographic detail available here: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics.

what is the vaccine adverse event rate for the 12-15 year olds? again look at the world wide systems for recording this information and remember only 1-10% of events are recorded, please break this down by type of adverse reaction.

All adverse events following immunisation (AEFI) are published in weekly reports at: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

Furthermore, there is no evidence to support your comment that only 1-10% of events are reported for all AEFIs. Anyone – a medical practitioner, nurse, government agency or member of the public can report an adverse reaction and the Ministry and Medsafe are encouraging reports to be lodged. The form to do so is available at: https://report.vaccine.covid19.govt.nz/s/.

I trust this 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.

Yours sincerely,

Chris James
Group Manager

Medsafe