MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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23 May 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202205545

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 22 April 2022 for information relating to the Pfizer COVID-19 vaccine (Comirnaty). I will respond to each part of your request is in turn:

> *Q1 - Is the information in the Pfizer Covid BNT162b2 injection, which is stated to be 'Missing' in the EMA RMP, which was updated last in February 2022, now 195 pages long, 'Missing Information,' repeatedly stated in previous updates of the EMA RMP, that would be relevant to children and young adults, disclosed to parents, 12 years -15 year olds and to young adults, during the informed consent process?*

The risk management plan (RMP) is created by the vaccine manufacturer and is submitted to medicine regulators as part of the vaccine approval and safety monitoring process. The RMP details Comirnaty vaccine risks, how these risks can be minimised, and how more information will be obtained about Comirnaty's risks and uncertainties (missing information). Missing information refers to information on the safety of the medicinal product that is currently missed or unknown. Some information continues to be collected during long-term use of the medicine. The Comirnaty data sheet, consumer medicine information (CMI) and the package leaflet give essential information for healthcare professionals and patients on how to use the vaccine.

Missing information is not included as part of the informed consent process for the Pfizer COVID-19 vaccine as it is not noted in the data sheet or CMI. It is important to note that Medsafe only approve medicine's that meet standards of safety, quality and efficacy.

> *Q2 - Why is there no reference to this Study C4591007 6 month analysis?*

A summary of the information from the 6 months analysis for Study C4591007 is contained in section 5 of the Comirnaty data sheet. The data sheet can be found on the Medsafe website here: www.medsafe.govt.nz/profs/Datasheet/c/Comirnaty0.2mlOrangeCapinj.pdf.

> *Q3 - Where is the evidence that the 6 month analysis of Study C4591007 was provided to Medsafe, by the 'Due Date,' of February 28, 2022, bearing in mind that the 5-11 year old 'vaccine' rollout, commenced on the 17th January 2022, which was 42 days 'before' the analysis request due date expired?*

Q4 - Was this analysis provided by Pfizer and if so, on what date?

Q5 - If the due date was extended, on what grounds was this justified, especially when the product was being administered in NZ, to 5-11 year olds, since the 17th January, 2022 and is still being administered?

Questions three, four, and five refer to condition eight of gazette notice 2021-go5403, relating Comirnaty (10mcg/0.2mL dose): "Provide the six months analysis data from Study C4591007. Due date: 28 February 2022".

The Ministry has identified one document in scope of your request. This document was provided by Pfizer to Medsafe on 28 February 2022 and refers to Study C4591007. Please note some information has been deemed out of scope and has been withheld under section 9(2)(a) of the Act, to protect the privacy of natural persons. I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

Q6 - Has there any been any due diligence exercised by Medsafe NZ, to access scientific evidence that evaluates potential, theoretical or risks, or reported adverse reactions, with 5-11 year olds, who have received the Pfizer Covid 'orange capped' vaccine, which contains Tromethamine and Tromethamine Hydrochloride as it's 'buffer,' which was not the same buffer that was used in the clinical trial?

This was assessed during the approval process and the safety data included is in the AEFI (adverse events following immunisation) report which can be found on the Medsafe website here: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

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 of Health website at: www.health.govt.nz/about-ministry/information-releases.

Yours sincerely

Chris James
Group Manager
Medsafe

Document 1

Regulatory Affairs Department Australia/New Zealand
Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000
Australia

The Manager
Medsafe
Ministry of Health, Ground Floor Reception
133 Molesworth Street, Thorndon
Wellington 6011
NEW ZEALAND

28 February 2022

Dear Sir, Madam

Re: Changed Medicine Notification - Change in Dosage

COMIRNATY COVID-19 mRNA vaccine (tozinameran)

Dose Form	Strength	Identifier	TT50
Concentrate for injection	0.1 mg/mL	(orange cap, must dilute) 10 mcg/0.2 mL dose	10853/1a
Suspension for injection	0.1 mg/mL	(grey cap, do not dilute) 30 mcg/0.3 mL dose	10853/1
Concentrate for injection	0.5 mg/mL	(purple cap, must dilute) 30 mcg/0.3 mL dose	10853

Please find enclosed a copy of the dossier of the Changed Medicine Notification for abovementioned products.

Proposed changes to the Data sheet (DS):

Out of Scope

[redacted]

Annotated and clean copies of proposed DS are provided under Module 1.3.1

Supporting data

Out of Scope

[redacted]

Document 1

Out of Scope

Vaccine Efficacy in children 5-11 years

In support of the proposed update of clinical information with data from C4591007 Vaccine efficacy in 5-11 years, following is provided.

2.5 Clinical Overview: Clinical Information amendment Vaccine efficacy in 5-11 years of age

Out of Scope

Declarations

We give the assurance that:

- The submission dossier complies with all requirements set out in CTD Module 1: Administrative information and prescribing information for Australia
- There have been no other changes made to the Product Information, other than those specified in this application.

Presentation of the Dossier

Modules 1, 2 and 5 have been provided via EFT.

Out of Scope

S9(2)(a)

Yours faithfully

S9(2)(a)

Senior Regulatory Affairs Associate