

Office of the Prime Minister

Prime Minister

Minister for National Security and Intelligence

Minister for Child Poverty Reduction

Minister Responsible for Ministerial Services

Associate Minister for Arts, Culture and Heritage



S Hill

By email: fyi-request-20909-39ff0f21@requests.fyi.org.nz

11 NOV 2022

Ref: PMO 2022-328

Tēnā koe S Hill

Official Information Act request relating to Testing of COVID-19 vaccine by Pfizer

Thank you for your Official Information Act 1982 (the Act) request, received on 18 October 2022. You requested:

"[1] In your capacity as Prime Minister were you aware (before October 2022) that Pfizer did NOT test whether the COVID-19 vaccine prevented transmission of the virus before it entered the market?"

"[2] During your public campaign drive where you repeatedly stated that the Pfizer Vaccine was "tested," "safe," and "effective" were you aware that Pfizer did NOT test whether the COVID-19 vaccine prevented transmission of the virus before it entered the market?"

Medsafe provides independent advice to the Government and approves all medicines and vaccines available in New Zealand. Medsafe evaluates applications to ensure that they comply with international standards and local requirements for quality, and that the expected benefits outweigh the risks of harm in the intended treatment population. Only then will Medsafe recommend approval for use in New Zealand.

Medsafe first recommended provisional approval to the Pfizer/BioNTech vaccine for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in February 2021. The relevant press release can be found on the Beehive website at: www.beehive.govt.nz/release/first-covid-19-vaccine-approved. Medsafe gave the Pfizer vaccine the original provisional approval and subsequent approvals because their own independent evaluations based on results of clinical trials concluded that the vaccine met the requirements for efficacy, safety, and quality. There is more information about COVID-19 vaccines currently approved by Medsafe for use in New Zealand, including Comirnaty (the Pfizer vaccine), available on the Medsafe website at: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp. Details of the approval process can be found here. The current status of specific COVID-19 vaccines, including the Pfizer vaccine, can also be found on the Medsafe website at: www.medsafe.govt.nz/COVID-19/status-of-applications.asp.

A detailed Data Sheet for healthcare professionals is available at:

www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf. This includes information relating to the efficacy of the vaccine in preventing first COVID-19 occurrence. On pages 11 and 12 of the Data Sheet it states:

"In the second primary analysis, efficacy of COMIRNATY in preventing first COVID-19 occurrence from 7 days after Dose 2 compared to placebo was 94.6% (95% credible interval of 89.9% to 97.3%) in participants 16 years of age and older with or without evidence of prior infection with SARS-CoV-2.

Additionally, subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across genders, ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.

Updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up through 13 March 2021, representing up to 6 months of follow-up after Dose 2 for participants in the efficacy population.

The updated vaccine efficacy information is presented in Table 4.” [Table of data can be found on the website].

More information on how COVID-19 vaccines work is available on the Ministry of Health website at: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/how-covid-19-vaccines-work. This includes details on how the efficacy of the Pfizer vaccine was measured.

The measures for the efficacy of COVID-19 vaccines were based on the prevention of COVID-19 disease, rather than on the prevention of transmission of the virus by someone already infected. However, by making it much less likely that someone will catch the virus, it logically reduces transmission since you can't transmit an infection if you are not infected. More information about the prevention of transmission of the virus by the Pfizer vaccine has been and continues to be gathered as it continues to be used widely throughout the world.

In general (not COVID-19-specific), there are two mechanisms through which vaccines can potentially reduce transmission:

1. Preventing infection of the vaccinated person (if a person is uninfected, they cannot transmit the virus). This is measured in vaccine efficacy/effectiveness against infection.
2. Reducing the number of onward infections (if the vaccinated person does become infected). This is measured by assessing the reduction in the number of transmissions to contacts of infected individuals.

These two methods combine to provide a larger effect than either of them in isolation.

For the Pfizer vaccine, there is a substantial body of evidence available about its ability to reduce the number of infections (and the subsequent effect on transmission through reduction of infection). It should be noted that data for vaccine effectiveness (against infection and onward transmission) for variants prior to Omicron have been monitored since trial data were first released by Pfizer in 2020. Vaccine effectiveness against infection was generally higher for previous variants than for Omicron.

At the time, purchasing responsibilities were transferred over to Ministry of Health, guided by recommendations from COVID-19 Vaccine Technical Advisory Group (CV TAG). Please refer to the links below:

Ministry of Health website providing information on the latest science and technical advice on COVID-19 including information on vaccine effectiveness and transmission:

www.health.govt.nz/covid-19-novel-coronavirus/covid-19-resources-and-tools/covid-19-science-news#variants

CV TAG takes into account a breadth of evidence, including vaccine effectiveness against infection, transmission: www.health.govt.nz/about-ministry/leadership-ministry/expert-groups/covid-19-vaccine-technical-advisory-group-cv-tag

Medsafe concluded through its approval process that the Pfizer vaccine had been tested and was safe and effective for the vaccine's use to protect individuals from the virus in New Zealand. This office does not hold any information about whether Pfizer had tested its COVID-19 vaccine for prevention of transmission of the virus prior to the vaccine entering the world market. Accordingly, your request is declined under section 18(e) of the Act on the basis that the information does not exist.

You have the right to ask the Ombudsman to investigate and review my decision under section 28(3) of the Act.

Ngā mihi nui,

A handwritten signature in blue ink, appearing to be 'Raj Nahna', written in a cursive style.

Raj Nahna
Chief of Staff