133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

5 October 2021

s 9(2)(a)

[redacted] [redacted]
Ref: H20211151

Tēnā koe [redacted]

Response to your request for official information

Thank you for your letter to the Ministry of Health (the Ministry) on 7 September 2021 requesting under the Official Information Act 1982 (the Act) a range of information related to the COVID-19 virus.

This letter replaced your request of 25 August 2021, which was also transferred to the Ministry by the Department of the Prime Minister and Cabinet on 7 September 2021 and by the Minister for COVID-19 Response, Hon Chris Hipkins, on 14 September 2021. Rather than quote your request verbatim, I have attached it as appendix 1.

Turning to the first part of your request, in paragraph 5 you outline an argument about lockdowns, PCR testing, the use of masks, vaccines and the calibre of advice the Ministry has received in responding to the COVID-19 pandemic. You then asked:

> *"Are the New Zealand doctors and scientists advising the MOH of this calibre? If the MOH disagrees with any of the above statements, please let me know."*

As the Ministry advised in its letter of 31 August 2021, when it sought to rescope your request, there is no requirement under the Act for agencies to create new information, compile information they do not hold or provide or prove an opinion. These questions and the statements that precede them are designed to engage in a debate about the Government's response to the COVID-19 pandemic rather than a request for official information. The Act does not support requests where an opinion, comment, argument, or hypothetical statement is put to the Ministry for response, couched as a request for information. These questions are therefore refused under section 18(g) of the Act on the grounds that the information sought is not held by the Ministry.

I can confirm that the Ministry stands by the quality of advice it has received and sought from a range of national and international sources as it has responded to the global COVID-19 pandemic.

I will now turn to part 2 of your request and its 17 questions, responding to each in turn.

1. *I have been unable to find a definition of COVID-19 or vaccine in the COVID-19 Public Health Response Act 2020 or other legislation. So, what is the MOH's definition of COVID-19 (i.e., the specific signs and symptoms) and a vaccine (i.e., the outcome)?*

The COVID-19 Public Health Response Act 2020 at section 5(2) says: *"Terms and expressions used and not defined in this Act, but defined in the Health Act 1956, have the same meanings as in the Health Act 1956."*

Schedule 1 of the Health Act (section B of part 1) lists COVID-19 as an infectious disease that must be notified to a medical officer of health. Additionally schedule 1 (part 3) also lists COVID-19 and *"novel coronavirus capable of causing respiratory disease"* as quarantinable infectious diseases. These amendments to schedule 1 were made by the Infectious and Notifiable Diseases Order (No 2) 2020 as an Order in Council signed by the Governor-General, Rt Hon Dame Patsy Reddy, on 9 March 2020. The order is publicly available at: www.legislation.govt.nz/regulation/public/2020/0031/latest/whole.html

Vaccines are not defined in the COVID-19 Public Health Response Act as vaccination does not form part of the purpose of that Act. The purposes of this law are outlined in section 4 which is available at: www.legislation.govt.nz/act/public/2020/0012/latest/whole.html#LMS344139.

Vaccines are medicines approved under the Medicines Act 1981. Section 3(1)(a) defines a "medicine" as:

> "any substance or article that is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, *immunological,* or metabolic means." [emphasis added].

Three COVID-19 vaccines have been provisionally approved for use in New Zealand under section 23 of the Medicines Act by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority. The *Gazette* notices, data sheets and other relevant information required by law for each approved vaccine are available at: www.medsafe.govt.nz/COVID-19/status-of-applications.asp

2. *I understand that a woman is in ICU at Auckland Hospital after taking the vaccine and has allegedly tested positive for COVID-19. Is the MOH adopted the Centre for Disease Control and Prevention ("CDC") (e.g., death and injuries within 14 days of the vaccine will be recorded as unvaccinated despite Fauci public comments that an immediate reaction could take up to approximately 40 days)? What is the MOH's policy regarding classifying this woman and others as being vaccinated or unvaccinated?*

The Ministry cannot comment on the policies of other nations, nor on remarks made by Dr Fauci. As I noted in my response to part 1 of your letter, the Act does not support requests where the Ministry is asked to comment on a statement put to it.

However, reports of breakthrough infections and specific side effects can be reported to the New Zealand Centre for Adverse Reactions Monitoring (CARM), at the University of Otago, which undertakes pharmacovigilance in New Zealand under contract to the Ministry. Information on reports for adverse events after COVID-19 vaccinations can be found at: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

3. *Is the mRNA Injection a medical treatment or a vaccine?*

Your references to "mRNA Injection" in this and the questions that follow have been interpreted as references to mRNA vaccines. Please see my response to the second part of your first question. Additional information about mRNA vaccines is available at: www.medsafe.govt.nz/COVID-19/mRNA-vaccines.asp.

4. *What is the relative risk reduction and absolute risk reduction for the mRNA injection?*

Information in response to this question is publicly available at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-effectiveness-and-protection.

5. *Please provide me with a copy of the benefit and risk assessment undertaken by the MOH regarding the provisional approval of the mRNA injection.*

The benefit and risk assessment undertaken by Medsafe for the provisional approval of the Pfizer Comirnaty vaccine has been previously released in a response under the Act (H202106950) on 13 August 2021. Part of your schedule 2 in your request headed *OIA Response – Safety and Efficacy* appears to be sourced from that previous release. Given you appear to already have the information, there is no requirement on the Ministry to release it to you again. However, the Ministry is considering proactively publishing that response.

6. *What are the MOH guidelines for informed consent for the mRNA injection?*

The Ministry has previously responded to questions related to consent in an earlier response under the Act which has been published at: www.health.govt.nz/system/files/documents/information-release/h202101370_12_march_2020_covid_vaccine_information_to_recipents.pdf.

There is additional information at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-resources.

7. *The Consumer Medicine Information Summary (CMIS) on Medsafe's website states that the mRNA Injection contains BNT162b2. However, it warns that people should not take the mRNA injection if they are allergic to the substance. So, what test does Medsafe recommend to ascertain whether a person is allergic to BNT162b2 or not (prior to taking the mRNA injection?*

As with any other vaccine or medication, the CMIS to which you have referred provides guidance to consumers prior to consenting to vaccination with the Pfizer Comirnaty vaccine. It specifically alerts the consumer to discuss with their doctor or vaccinator if they have had a severe allergic reaction or breathing problems after any other vaccine or when they received their first dose of Comirnaty. The information sheet available to consumers (https://covid19.govt.nz/assets/resources/Vaccine-resources/getting-your-COVID-19-vaccine-what-to-expect.pdf) outlines several things to be considered before vaccination including whether the person has had a severe or immediate allergic reaction to any vaccine or injection in the past, or if they are on blood-thinning medications or have a bleeding disorder.

As the CMIS notes some people may have an allergic reaction that cannot be predicted or prevented. It is for this reason that consumers are required to remain on site for 15 minutes after vaccination as this is the time when signs of an allergic reaction are most likely to appear, allowing such reactions to be quickly identified and treated.

The Ministry has also contracted the Immunisation Advisory Centre at the University of Auckland to provide comprehensive training for COVID-19 vaccinators that includes both online and face-to-face practical sessions. A key part of vaccination training focuses on discussing with consumers their prior medical history (such as allergies) as well as having received CPR and anaphylaxis training.

Vaccinators work under the supervision of a clinical supervisor who is immediately available to support the vaccinator in the event of an adverse reaction. There is more information about COVID vaccine training at: https://covid.immune.org.nz/education/joining-covid-19-

workforce/joining-covid-19-workforce-education-profession. Information about the COVID-19 vaccine workforce and the roles and responsibilities of vaccinators and clinical supervisors at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-strategy-planning-insights/covid-19-expanding-vaccinator-workforce.

8. *Please let us know which cultures are included under "Polynesian" and "Asian" in the OIA document set out in Schedule 3.*

There was no schedule 3 attached to your request; we have inferred that you are referring to the part of schedule 2 in your request headed *OIA Response – Safety and Efficacy.* While you were asked on 9 September 2021 to provide any further information about when this excerpt was released and its reference number, a reply was not received.

However, as noted in my response to question 5, this has been identified as information that has been previously released in a response under the Act (H202106950) on 13 August 2021. The document was the Clinical Evaluation of the Comirnaty vaccine dated January 2021 based on data received from Pfizer/BioNTech until mid-November 2020.

The standard guidance for the collection of race and ethnicity data in clinical trials is outlined on the United States Food and Drug Administration (FDA) website at: www.fda.gov/media/75453/download (please refer to page 10).

9. *How many breakthrough cases have been reported (in any form) to the MOH?*

Please find the table below information about the vaccination status of people found to have COVID-19 both in the community and managed isolation and quarantine facilities (MIQF) from 17 August 2021 to 15 September 2021. Please note that currently the MIQF cases only relate to those people vaccinated in New Zealand.

Please note that most people infected with COVID-19 are unvaccinated. However, as with any vaccine, 'breakthrough cases' are to be expected as a virus mutates, and new variants emerge. Vaccination remains the best way to slow the spread of COVID-19 and prevent infection by the virus and its variants. The COVID-19 vaccine not only protects people from getting infected and severely ill, but also significantly reduces the likelihood that an infected person will need to be hospitalised or die. The Ministry compiles regular updates of published research and these are publicly available at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-resources-and-tools/covid-19-science-news#variants

Vaccination status when reported	**Community**	**MIQF**
No doses received prior to being reported as a case	829	66
1 dose only, received less than 14 days before reported as a case	73	0
1 dose only, received at least 14 days before reported as a case	53	2
Fully vaccinated but second dose less than 14 days before reported as a case	16	0
Fully vaccinated at least 14 days before reported as a case	31	10

10. *How many alleged deaths and serious adverse reactions from the mRNA Injection have been reported (in any form) to the MOH which have not been posted on the CARM website?*

Medsafe publishes all adverse effects following immunisation (AEFI), including deaths, every Wednesday at: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp. Each report is published about two weeks after it is dated.

As noted in my response to question 2, CARM undertakes pharmacovigilance in New Zealand under contract to the Ministry. While anyone – doctors, nurses, pharmacists, pharmaceutical companies, government agencies or a member of the public – can report an adverse reaction to CARM, reporting is voluntary. Both Medsafe and CARM continue to encourage the reporting of all AEFI at: https://report.vaccine.covid19.govt.nz/s/.

11. *Does the Spike Protein from the mRNA injection move from the muscle in the arm from where it is injected and travel to other parts of the body, causing harm?*

Information about how mRNA vaccines actually work is available at: www.medsafe.govt.nz/COVID-19/mRNA-vaccines.asp. As the Ministry advised in its letter of 31 August 2021, there is a wide range of peer-reviewed scientific research about the COVID-19 virus, including the efficacy of mRNA vaccines and the spike protein, on *PubMed,* a website of 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.

12. *Please could you provide a copy of the contract between the Government and Pfizer and/or BioNTech for the mRNA Injection? Furthermore, if the MOH claims commercial sensitivity (notwithstanding that the taxpayers are paying for the mRNA Injection, please advise if Pfizer is liable for fraud, negligence, and/or malice regarding the mRNA Injection despite the immunity that the Government has granted Pfizer.*

The contract between the Government and Pfizer, and information relating to its provisions, is withheld in full under section 9(2)(b)(ii) of the Act on the grounds that its release would likely unreasonably prejudice the commercial position of the person who supplied the information.

13. *How many claims have been accepted, in progress or declined by the Accident Compensation Corporation concerning the mRNA vaccine?*

This part of your request was transferred to the Accident Compensation Corporation (ACC) on 10 September 2021. You can expect a response from ACC in due course.

14. *Do the PCR Test protocols establish diagnostic specificity for clinical use (i.e., detect a viral infection or COVID-19), or does the PCR Test report on analytical specificity (i.e., amplify the target genetic sequences) and is there any value in testing asymptomatic and healthy people? If so, please provide the details.*

The PCR test identifies specific parts of the genetic material (mRNA) from the SARS-CoV-2 virus and amplifies these sequences until they are detectable. The number of amplifications gives an indication of viral load as an inverse relationship. The analytical sensitivity and specificity of assays used in New Zealand diagnostic laboratories have been determined by the laboratories and/or the manufacturers. The clinical sensitivity and specificity of assays for the detection of SARS-CoV-2 in COVID-19 infected individuals has been determined in numerous settings globally. The Ministry does not conduct any studies or research regarding this. However, there are many individual studies and several systematic reviews available for your reference on this topic, including on *PubMed,* a service of the National Library of Medicine: https://pubmed.ncbi.nlm.nih.gov/?term=covid+19+laboratory+diagnosis.%C2%A0

There is value in testing people who have no symptoms but may be infected by SARS-CoV-2 as this can identify an asymptomatic (or pre-symptomatic) infection and reduce the risk of further transmission by isolating that person.

15. *Is the MOH, or does the MOH intend to, follow the CDC's policy of running higher cycle thresholds (e.g., 40) for the unvaccinated and lower thresholds (e.g., 28) for the vaccinated. If so, please provide the details.*

The Ministry is unable comment on policies of other nations' agencies. However, for the RT-PCR assays being used in New Zealand laboratories, the number of cycles for which the assays run is typically 40. The number of cycles for which any RT-PCR assay runs is a pre-programmed parameter in the software of the analyser used for the test and cannot be changed by the individual laboratories using the assays. Regardless of when the threshold is reached, the assay will run for the full 40 cycles.

The number of cycles for which the assays run has not been changed over the time during which testing for COVID-19 has been occurring in New Zealand. The variants of COVID-19 (including the delta variant) are determined by Whole Genome Sequencing. Detailed information on genome sequencing can be found on the genome sequencing Q&A on the website of the Institute of Environmental Science and Research at: www.esr.cri.nz/our-expertise/covid-19-response/new-news-page/

16. *Does the MOH hold any information that shows that the PCR Test can differentiate between SARS-CoV-19 (sic) and/or COVID 19 and influenza? If so, please provide the details.*

The PCR Test used in New Zealand can differentiate between SARS-CoV-2 and influenza. Presumably this question has been prompted by misinformation about the Centers for Disease Control's (CDC) decision to withdraw the FDA Emergency Use Authorisation for a PCR test it developed early in the pandemic. There is more information about this issue at: www.factcheck.org/2021/07/scicheck-viral-posts-misrepresent-cdc-announcement-on-covid-19-pcr-test/.

The withdrawal of the PCR test developed by the CDC does not affect the PCR testing undertaken by New Zealand diagnostic laboratories. The CDC's RT-PCR test was only looking for SARS-CoV-2 and ignoring genetic material from other viruses. The changes to testing procedures were to encourage labs to switch to tests that can look for flu viruses at the same time. The CDC's announcement about the changes to RT-PCR testing for COVID-19 can be found at: www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html.

17. *Is the MOH requiring diagnostic labs in New Zealand to test against certified reference materials (i.e., physical specimens) instead of using digital libraries with a computer genetic sequence to flag COVID-19? If so, please provide the details.*

The Ministry requires diagnostic laboratories to operate in accordance with the standards the laboratories are accredited to. This requirement to test against certified reference materials is set out in the accreditation requirements for ISO 15189, which is the international standard that specifies the requirements for quality and competence of medical laboratories. A list of accredited COVID-19 testing laboratories in New Zealand is available at: www.ianz.govt.nz/resources/covid-19-laboratories. You may want to contact International Accreditation New Zealand for more information about ISO 15189 and its accreditation work by contacting them directly at: info@ianz.govt.nz.

Finally, on 13 September 2021, another requester forwarded your rescoped request to the Ministry. The email to which the rescoped request was attached included the following remarks from you on 7 September 2021:

> *"Please find attached my response to the MOH in respect of the request to rescope my original letter. As some of you know, I never intended to make a "proper" OIA request in the first letter as I have the answers to most of the questions. It was about ensuring that all the MP had the information and using it to educate NZders that were on the fence. We will reach 11,000 signatures on the petition tonight."*

The Ministry has invested significant time and effort to meet its obligations under section 13 to render all reasonable assistance in answering the questions you have posed. Given the Ministry is leading New Zealand's health response to a global pandemic, please be advised that making requests to which you already know the answers could be deemed vexatious or frivolous and refused under section 18(h) of the Act.

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, will be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases.

Nāku noa, nā

Dom Harris
Manager – Office of the Deputy Chief Executive
COVID-19 Health System Response

Ministry of Health
133 Molesworth Street
Wellington

7 September 2021

By email

Attention: Nick Allan

Dear Nick

Official Information Request – Ref: H2020111151

1. Thank you for your email dated 31 August 2021 (a copy is set out at **Schedule 1**). This letter is divided into two parts:

   (a) **Part 1**: My response to your letter; and
   (b) **Part 2**: 17 questions under the Official Information Act ("**OIA**").

Part 1: My Response to your Letter

2. Thank you for asking after my husband and trusting that he is in good health and coping well with the current alert level restrictions. As you asked, the answer is **no**.

3. My husband went for regular blood tests last week after we were released from level 4. The results were alarming. The threshold for one test should have been under 60, and his result was 911. There has been a delay in getting the urgent scan due to the *"COVID-19 paperwork"*. It is shocking to other Kiwis and me that a sick man cannot access an urgent medical scan (even with medical insurance) due to the lockdown for a virus (including Delta[1]) which is comparable to the flu[2] , and the death rate has been inflated[3].

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/997414/Variants_of_Concern_VOC_Technical_Briefing_16.pdf
[2] https://www.who.int/bulletin/volumes/99/1/20-265892.pdf
[3] https://www.cdc.gov/nchs/data/health_policy/covid19-comorbidity-expanded-12092020-508.pdf

4. While I appreciate your prompt response, I am surprised that the Ministry of Health ("**MOH**") cannot answer the 100 questions I presented to them along with references.

5. Given the draconian measures which are being implemented for our *"health and safety"*, I would assume that the MOH would have undertaken extensive research and maybe even referred matters to an independent panel prior to the MOH advising the Government to:

   (a) **Lockdowns**: use the lockdowns as the primary control method despite scientific studies showing the lack of infectivity of asymptomatic SARS-CoV-2[4][5][6] (including the study of nearly 10,000,000 people in Wuhan) and the lack of any significant benefits[7][8][9][10][11]. The *COVID-19.live* website shows that as of 6/9/21, the MOH has undertaken 3,057,343 tests in the last 18 months and had 3,792 confirmed cases, 3036 recovered cases and 27 deceased. Yet, the MOH continues to *"test, test, test"* asymptomatic and healthy people instead of focusing on actual cases of sick people.

   (b) **PCR Test**: use the PCR test above 35 cycles (as per the OIA Response set out at **Schedule 2**). In July 2020, in a **"This Week In Virology"**, **Dr Fauci**[12] broadcast from his office at the **National Institute of Allergy and Infection Disease** that *"…If you get [perform the test at] a cycle threshold of 35 or more…the chances of it being replication-competent [aka accurate] are minuscule…you almost never can culture virus [detect a true positive result] from a 37 threshold cycle…even 36…"*.

   Recently, a Portuguese Court[13] ruled that concerning PCR Tests *"the eventual reliability of the PCR tests carried out depends, from the outset, on the threshold of amplification cycles they support, such that, up to the limit of 25*

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4 Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China - PubMed (nih.gov)
5 https://pubmed.ncbi.nlm.nih.gov/32513410/
6 2005.02090.pdf (arxiv.org)
7 https://onlinelibrary.wiley.com/doi/full/10.1111/eci.13484
8 Effects of non-pharmaceutical interventions on COVID-19: A Tale of Three Models | medRxiv
9 Did lockdowns really save 3 million COVID-19 deaths, as Flaxman et al. claim? – Nicholas Lewis
10 Smart Thinking, Lockdown and COVID-19: Implications for Public Policy by Morris Altman :: SSRN
11 Did Lockdown Work? An Economist's Cross-Country Comparison by Christian Bjørnskov :: SSRN
12 https://asm.org/Podcasts/TWiV/Episodes/COVID-19-with-Dr-Anthony-Fauci-TWiV-641 (4.29 mins)
13 https://translate.google.com/translate?hl=&sl=pt&tl=en&u=http%3A%2F%2Fwww.dgsi.pt%2Fjtrl.nsf%2F33182fc732316039802565fa00497eec%2F79d6ba338dcbe5e28025861f003e7b30

cycles, the test reliability will be around 70%; if 30 cycles are performed, the degree of reliability drops to 20%; if 35 cycles are reached, the degree of reliability will be 3%.".

(c) **Mandating masks**: despite the lack of credible scientific evidence supporting the politics of masks[14] [15] [16](which include wearing a t-shirt over your face in New Zealand).

The **United States Surgeon General**, **Dr Fauci**, the **World Health Organisation**, **Ms Adern,** and **Dr. Bloomfield** have all stated masks are ineffective. There was no need to wear masks unless you had respiratory symptoms. The message was that masks do not work. The reason being that masks do not stop viral transmission as microscopic coronavirus particles are approximately 1000 times smaller than the pores in conventional masks (hence the disclaimers on many boxes). Scientists and doctors suggest that masks may contribute to spreading viruses faster due to transmission of the virus from re-using masks and wiping the used mask over objects (there are no hazmat bins to dispose of the masks) and trapping the virus in the mask and breathing it in.

(d) **Vaccine**: it is unknown if the vaccine prevents contraction or transmission of SARS-CoV-19 or COVID-19[17] [18] [19] [20], but it may reduce some milder symptoms in sick people[21] [22] [23]. In addition, there are numerous reports of breakthrough cases in the vaccinated[24] [25] [26] [27], particularly in the most vaccinated countries such as Israel[28] and Gibraltar.

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[14] Universal Masking in Hospitals in the Covid-19 Era | NEJM
[15] https://pubmed.ncbi.nlm.nih.gov/17238820/
[16] Masks-Final.pdf (vaxxter.com)
[17] https://www.medsafe.govt.nz/COVID-19/q-and-a.asp
[18] Safety and Immunogenicity Study of 2019-nCoV Vaccine (mRNA-1273) for Prophylaxis of SARS-CoV-2 Infection (COVID-19) - Full Text View - ClinicalTrials.gov AND A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19 - Full Text View - ClinicalTrials.gov AND https://clinicaltrials.gov/ct2/show/NCT04368728
[19] Melbourne couple meet newborn baby eight days after birth due to COVID restrictions, Queensland news (9news.com.au) and https://www.msn.com/en-au/news/melbourne/couple-finally-meet-newborn-eight-days-after-birth/ar-AAKTKcu
[20] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01290-3/fulltext
[21] https://finance.yahoo.com/news/fauci-vaccines-will-only-prevent-symptoms-not-block-the-virus-195051568.html
[22] https://www.bmj.com/content/bmj/371/bmj.m4037.full.pdf
[23] https://www.clinicaltrials.gov/ct2/show/NCT04848584?cond=pfizer+vaccine&draw=2&rank=1
24 https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html
25 https://planetes360.fr/pr-luc-montagnier-les-variants-viennent-des-vaccinations/ and https://planetes360.fr/pr-luc-montagnier-les-variants-viennent-des-vaccinations/
26 SPI-M-O: Summary of further modelling of easing restrictions – Roadmap Step 2, 31 March 2021 - GOV.UK (www.gov.uk)
27 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4516275/
28 https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(21)00367-0/fulltext

There are also concerns that the current vaccines are ineffective against the numerous variants[29]. This concern is juxtaposed with reports that natural immunity[30] [31] [32] [33] [34] [35] and vitamin D[36] [37] [38] [39]are important factors in the "fight as COVID-19".

I have been provided with a copy of the OIA information set out in **Schedule 3**. The OIA information shows that MedSafe did not grant full approval as several issues remained unresolved and additional safety and efficacy data was needed for the so-called "safe and effective" mRNA injection (especially the efficacy in people of Polynesian and Asian ethnicity, which surprises me given that the advertising campaigns target these groups). In addition, distinguished international scientists and doctors have raised similar concerns, but the fourth estate does not publish and broadcast concerns being raise from the likes of (to name just a few):

- **Dr. Beda Stadler**, PhD, is considered the "vaccine pope" and one of the top immunologists in the world.
- **Dr. John Ioannidis**, MD, DSc, is Professor of Medicine, of Epidemiology and Population Health, and (by courtesy) of Biomedical Data Science, and of Statistics and co-Director of the Meta-Research Innovation Center at Stanford (METRICS). Dr. Ioannidis is one of the most-cited scientists of all time in the scientific literature. His current research at Stanford covers a wide agenda, including meta-research, large-scale evidence, population health sciences and predictive medicine and health.
- **Dr. Peter McCullough**, MD, MPH is one of the most cited MD's in the world in the National Library of Medicine on medical treatments, including for COVID-19, and has served on committees to investigate vaccine injuries.
- **Dr. Sucharit Bhakdi**, MD, is a renowned German microbiologist who has published over three hundred articles in the fields of immunology, bacteriology,

29 https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1
30 https://www.merck.com/news/merck-discontinues-development-of-sars-cov-2-covid-19-vaccine-candidates-continues-development-of-two-investigational-therapeutic-candidates/
31 https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1
32 https://www.medrxiv.org/content/10.1101/2021.04.19.21255739v2
33 Exposure to SARS-CoV-2 generates T-cell memory in the absence of a detectable viral infection | Nature Communications
34 Your Immune System Evolves to Fight Coronavirus Variants - Scientific American
35 Immunity to Respiratory Viruses (researchgate.net)
36 Vitamin D deficiency and COVID-19: A case-control study at a tertiary care hospital in India - PubMed (nih.gov)
37 Vitamin D and Its Potential Benefit for the COVID-19 Pandemic - PubMed (nih.gov)
38 Vitamin D supplementation and COVID-19 risk: a population-based, cohort study (nih.gov)
39 Vitamin D deficiency and the COVID-19 pandemic - PubMed (nih.gov)

virology, and parasitology, and received numerous awards and the Order of Merit of Rhineland-Palatinate. He is also the former Emeritus Head of the Institute for Medical Microbiology and Hygiene at the Johannes-Gutenberg-Universität in Mainz, Germany.

- **Dr. Mike Yeadon**, PhD, is the former Vice President and a Chief Scientist of Allergy and Respiratory at Pfizer.
- **Dr. James Lyon-Weiler**, PhD, Senior Research Scientist, University of Pittsburgh
- **Dr. Jim Meehan**, MD, is a former editor of two medical journals.
- **Dr. John Lee**, PhD, is a pathologist and former clinical professor of pathology at Hull York Medical School and is a Consultant Histopathologist at Rotherham NHS Foundation Trust.
- **Dr. Roger Hodkinson** MA, MB, FRCPC, FCAP is a medical specialist in pathology and virology and is currently Chairman of a medical biotechnology company in North Carolina that produces COVID-19 tests. He has also been used as a medical expert in court.
- **Dr. Denis Raincourt**, PhD, Researcher and former full Professor of Physics at Hull University in Ottawa, Canada
- **Dr. Christine Northrup**, MD, is one of the most respected women in America on women's health issues and a former guest on numerous television shows, including Oprah Winfrey.
- **Dr. Sheri Tennpenny** is an expert on vaccine safety for families.
- **Dr. Dolores Cahill** received her PhD in Immunology from Dublin City University in 1994 and is a professor at the University College in Ireland. She was a Member of Ireland's Advisory Science Council (2005-2014), a European Commission Seconded National Expert (2013-2014) and an EC expert for over 10 years.
- **Dr Tess Lawrie** (MBBCh, DFSRH, PhD). Her peer-reviewed publications have received in excess of 3000 citations, and her ResearchGate score is among the top 5% of ResearchGate members.
- **Dr Byram Bridle**, a viral immunologist and associate professor at the **University of Guelph, Ontario.**
- **Dr Stuart White,** in his letter to the editor of the **British Medical Journal**

6. Are the New Zealand doctors and scientists advising the MOH of this calibre?

7. If the MOH disagrees with any of the above statements, please let me know.

8. Please note that I do not expect the MOH to ask questions of 2000 people at the MOH, as you claim. Therefore, to keep matters simple, I will only ask the following 17 questions for the time being. We can address the questions in my previous letter on another occasion.

Part 2: Questions under the OIA Request

9. Please could you provide me with the following information for the following 17 questions:

Definition Questions

(1) I have been unable to find a definition of COVID-19 or vaccine in the COVID-19 Public Health Response Act 2020 or other legislation. So, what is the MOH's definition of COVID-19 (i.e., the specific signs and symptoms) and a vaccine (i.e., the outcome)?

(2) I understand that a woman is in ICU at Auckland Hospital after taking the vaccine and has allegedly tested positive for COVID-19. Is the MOH adopted the **Centre for Disease Control and Prevention** ("**CDC**")[40] (e.g. death and injuries within 14 days of the vaccine will be recorded as unvaccinated despite Fauci public comments that an immediate reaction could take up to approximately 40 days)? What is the MOH's policy regarding classifying this woman and others as being vaccinated or unvaccinated?

Vaccines Questions

I request the following information concerning the COMIRNATY® messenger RNA (mRNA) based vaccine and other vaccines that are under provisional approval in New Zealand ("**mRNA Injection**").

(3) Is the mRNA Injection a medical treatment or a vaccine?

[40] Wayback Machine (archive.org)

(4) What is the relative risk reduction and absolute risk reduction for the mRNA Injection?

(5) Please provide me with a copy of the benefit and risk assessment undertaken by the MOH regarding the provisional approval of the mRNA injection?

(6) What are the MOH guidelines for informed consent for the mRNA Injection?

(7) *The Consumer Medicine Information Summary* ("**CMIS**") on Medsafe's website[41] states the mRNA Injection contains BNT162b2. However, it warns that people should not take the mRNA Injection if they are allergic to the substance. So, what test does Medsafe recommend to ascertain whether a person is allergic to BNT162b2 or not (prior to taking the mRNA Injection)?

(8) Please let us know which cultures are included under "Polynesian" and "Asian" in the OIA document set out in Schedule **3**.

(9) How many breakthrough cases have been reported (in any form) to the MOH?

(10) How many alleged deaths and serious adverse reactions from the mRNA Injection have been reported (in any form) to the MOH which have not been posted on the CARM website?

(11) Does the Spike Protein from the mRNA Injection move from the muscle in the arm from where it was injected and travel to other parts of the body, causing harm?

(12) Please could you provide a copy of the contract between the Government and Pfizer and/or BioNTech for the mRNA Injection? Furthermore, if the MOH claims commercial sensitivity (notwithstanding that the taxpayers are paying for the mRNA Injection), please advise if Pfizer is liable for fraud, negligence, and/or malice regarding the mRNA Injection despite the immunity that the Government has granted Pfizer.

[41] https://medsafe.govt.nz/consumers/CMI/c/comirnaty.pdf

(13) How many claims have been accepted, in progress or declined by the Accident Compensation Corporation concerning the mRNA Vaccine?

PCR Tests Questions

(14) Do the PCR Test protocols establish diagnostic specificity for clinical use (i.e., detect a viral infection or COVID-19), or does the PCR Test report on analytical specificity (i.e., amplify the target genetic sequences) and is there any value in testing asymptomatic and healthy people? If so, please provide the details.

(15) Is the MOH, or does the MOH intend to, follow the CDC's[42] policy of running higher cycle thresholds (e.g., 40) for the unvaccinated and lower thresholds (e.g.,28) for the vaccinated? If so, please provide the details.

(16) Does the MOH hold any information that shows that the PCR Test can differentiate between SARS-CoV-19 and/or COVID 19 and influenza? If so, please provide the details.

(17) Is the MOH requiring diagnostic labs in New Zealand to test against certified reference materials (i.e., physical specimens) instead of using digital libraries with a computer genetic sequence to flag COVID-19? If so, please provide the details.

10. I look forward to your response.

Yours sincerely

[redacted]

[42] https://www.cdc.gov/vaccines/covid-19/downloads/Information-for-laboratories-COVID-vaccine-breakthrough-case-investigation.pdf

Schedule 1

Copy of MOH Response Letter dated 31 August 2021

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

31 August 2021

[redacted]

Ref: H202111151

Tēnā koe [redacted]

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 25 August 2021 for a range of information related to the COVID-19 virus. Given your request is 32 pages long, I have not repeated its contents but attached it as appendix 1.

While you addressed your letter to the Chief Executive of the Department of the Prime Minister and Cabinet, you also sent it to the Ministry and the Ministry is responding on behalf of both agencies.

I trust this letter finds you and your family, and especially your husband, in good health and coping well with current alert level restrictions.

I am seeking under section 15(1AA) of the Act to rescope your request. Excluding the many questions in your covering letter to members of Parliament, the schedules of your request contain more than 100 bullet pointed questions. Many of these in bullet points in turn contain several sub-questions accounting for about 200 questions. Additionally, you have directed that the scope of your request includes any/all information held by the Ministry, including the Director-General of Health, officers, committee members, employees and contractors, as well as five Ministers or Associate Ministers the Ministry supports. This accounts for about 2000 people.

In its current form your request would likely be refused under section 18(f) of the Act on the grounds that it would require substantial research and collation. Those requirements have been compounded by the recent outbreak of the highly infectious delta variant of COVID-19 which has required the Ministry divert significant resources to responding to the outbreak, while most employees are working from home. The Ministry is simply unable to quiz every employee, contractor or committee member as to whether they have read or hold any information about a specific piece of research you have cited.

Under section 15(1AA) the Ministry therefore asks you to identify those substantive questions you are seeking answers for.

When rescoping your request, please consider two points. First, since the global pandemic began more than a year ago, the Ministry and other government agencies have proactively published a significant amount of information about COVID-19 that could answer many of your questions. I want to draw your attention to the following:

- Comprehensive information about New Zealand's COVID-19 response, including vaccination, alert levels, overseas travel and departure tests, is available on the Unite against COVID-19 website at: www.covid19.govt.nz.

- COVID-19 case numbers are published daily by the Institute of Environmental Science and Research (ESR): https://nzcoviddashboard.esr.cri.nz/#!/. ESR has also published information a wide range of other information about the SARs CoV-2 virus and its response work: www.esr.cri.nz/our-expertise/covid-19-response/.

- The Ministry also publishes COVID-19 case data (www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-current-cases), COVID-19 Situation Reports (www.health.govt.nz/about-ministry/information-releases/general-information-releases/covid-19-situation-reports-january-november-2020) and COVID-19 vaccination data (www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-vaccine-data).

- New Zealand's Medicines and Medical Devices Authority, Medsafe, has published a range of information on the approval of COVID-19 vaccines, including adverse events following immunisation at: www.medsafe.govt.nz/index.asp.

- The Ministry has published responses to requests under the Act that cover many of the issues you have raised at, including around PCR testing and the isolation of the COVID-19 virus: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

- Additionally, 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.

The second point concerns the nature of requests under the Act. The Act allows New Zealanders to request official information from Ministers and government agencies. However, there is no requirement under the Act for Ministers and government agencies to create new information, compile information they do not hold or provide or prove an opinion. Many of your questions appear to be an attempt to engage in a debate about the Government's response to the COVID-19 pandemic rather than as requests for official information under the Act. The Act does not support requests where an opinion, comment or hypothetical statement is put to the Ministry for response, couched as a request for information. Many of your questions in the six schedules to your letter fall into this category are likely to be refused.

I look forward to hearing from you and would appreciate a response by 7 September 2021.

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.

Nāku noa, nā

Nick Allan
Manager, OIA Services
Office of the Director-General

Schedule 2

OIA Response – PCR Test Cycles

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

[redacted]

By email: [redacted]
Ref: H202007723

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 10 October 2020 for information relating to COVID-19 testing. I have responded to each part of your request below.

"Could you provide the details of which assay test, or tests, or kit or kits, have been used in NZ, in order to test SARS CoV-2 consumers/patients, in regard to serology, for antibodies, to date, with symptomatic or asymptomatic people?"

The following have been used to test for SARS CoV-2 in New Zealand:

- Roche Elecsys SARS-CoV-2 Nucleocapsid Total antibody assay (ECL methodology)
- Euroimmun SARS-CoV-2 Nucleocapsid IgG assay (microplate ELISA methodology)
- Vircell VirClia SARS-COV-2 monotest IgG (Spike 1 & Nucleocapsid)
- Abbott Architect SARS-COV-2 IgG (Nucleocapsid)

"Could you also provide conclusions reached, as to the reliability of those tests assays and kits?"

The Ministry of Health (the Ministry) does not hold this information, as such this part of your request is refused under section 18(g) of the Act. Conclusions on reliability are decided by each individual laboratory.

"I would in addition, like to know what if any T Cell serological testing is planned for NZ citizens and when these will be utilised, appreciating that antibodies wane or disappear and yet T Cells may be detected, which confer immunity? I am aware also, that some people do not elicit an antibody response, but will elicit a cell mediated or T Cell response."

The Ministry is not aware of any plans to introduce this kind of testing. As such this part of your request is refused under section 18(e) of the Act as the information does not exist.

"Can you address why NZ ESR labs and Otago University, are using Ct thresholds of 40-45, for PCR testing with this virus? International molecular biological standards and recommendations demonstrate, that at those levels, amplification can result in false or cold positives, because of the detection of non infectious remnants of the virus and other contaminants.

It has been shown in the scientific literature, that at such high thresholds, the results can be misinterpreted to return a positive result."

On 30 October 2020 this part of your request was transferred to the Institute of Environmental Science and Research (ESR) under section 14 of the Act. You can expect a response from ESR in due course.

"What processes that NZ technicians use, eliminate those types of misleading results, when utilising Ct thresholds of 40-45?"

Internal Quality Assurance is a routine part of standard laboratory practice in the laboratories undertaking COVID-19 testing in NZ, all of which are International Accreditation New Zealand (IANZ) accredited. Quality Control measures provide assurance, for each and every batch of tests run, that the reported results are reliable.

Additionally, all labs participate in External Quality Assurance Programmes for COVID-19 testing which present an external, random challenge and allow labs to monitor how their results compare to those of other labs performing COVID-19 testing by the same or different methodology. Any variance in results would be investigated thoroughly, including review of patient results from the same run. Polymerase Chain Reaction (PCR) tests utilised in our accredited laboratories typically run for 40 cycles.

All diagnostic laboratories are aware of the possibility that non-specific off-target amplification can occur beyond 37 cycles which can then generate non-specific amplification curves. Therefore, all weak positive signals are viewed with caution and the test repeated from sample using another real-time reverse transcription PCR test to exclude any contamination or off-target binding issues.

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.

Please note that this response, with your personal details removed, may be published on the Ministry website.

Yours sincerely

Dr Kelvin Watson
Group Manager COVID-19 Immunisation, Testing and Supply
COVID-19 Health System Response

Schedule 2

OIA Response – Safety and Efficacy

Xie X, Zou J, Fontes-Garfias C et al. Neutralization of N501Y mutant SARS-CoV-2 by BNT162b2 vaccine-elicited sera. bioRxiv preprint https://doi.org/10.1101/2021.01.07.425740

Final Recommendation

A number of quality issues, and some clinical issues arising from this application still remain unresolved. The applicant has committed to providing the outstanding information to address these issues, with many of these issues aligning with the EMA/CHMPs specific obligations that were listed in the EU's conditional approval. Due to this outstanding information the product cannot be recommended for consent under Section 20 of the Medicines Act 1981 for distribution in New Zealand. However, due to the COVID-19 global pandemic situation and the clinical need for the product, provisional consent under Section 23 of the Medicines Act 1981 may be considered for the following indication:

COMIRNATY is indicated for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

It is proposed that any provisional consent include the following conditions:

Provisional consent is to be granted for a period of nine months to address an urgent clinical need.

Provisional consent may only be renewed if the sponsor fulfils the following obligations within specified timelines, the dates of which may be altered on mutual agreement between Medsafe and the sponsor:

1) Prepare a Dear Healthcare Professional letter or comparable instructive material and provide this to Medsafe for review and approval prior to distribution of this product. Due date: February 2021.
2) The New Zealand site of batch release will only release batches for distribution in New Zealand once the importer or sponsor has verified that the shipping temperature profile meets specifications.
3) Provide Certificates of Analysis to Medsafe for the first three batches of vaccine intended to be distributed in New Zealand.
4) Provide data to further characterise the truncated and modified mRNA species present in the finished product. Data are expected to cover batches used in clinical trials (for which the characterisation data could be available earlier) and the PPQ batches. These data should address results from ion pairing RP-HPLC addressing 5'cap levels and presence of the poly(A) tail. These data should also address the potential for translation into truncated S1S2 proteins/peptides or other proteins/peptides. Relevant protein/peptide characterisation data for predominant species should be provided. Any homology between translated proteins (other than the intended spike protein) and human proteins that may, due to molecular mimicry, potentially cause an autoimmune process should be evaluated. Due date: July 2021, Interim report: March 2021.
5) Provide the analysis of the main peak of the RNA integrity test representing the full-length RNA, that addresses 5'cap levels and presence of the poly (A) tail. Due date: July 2021, Interim report: March 2021.
6) Provide the reassessment of the active substance specification for the DNA template purity and impurities. Due date: July 2021.

Document 7

7) Provide active substance process validation data regarding the finalised indirect filter qualification assessment and the shipping validation between sites. Due date: July 2021.
8) Comprehensively describe the capability of the next generation sequencing technology

Document 7

51) Provide regular updates on the duration of efficacy and the requirement for booster doses. This should include the six months analysis data from Study C4591001. Interim report due: April 2021.

52) Provide updates on efficacy including regarding asymptomatic infection in the vaccinated group, vaccine failure, immunogenicity, efficacy in population subgroups and results from post-marketing studies, when these become available.

53) Submit the final Clinical Study Reports for Study C4591001 and Study BNT162-01 once they become available.

54) Submit periodic safety update reports (including monthly reports) once they are available.

55) Inform Medsafe of all safety reviews they conduct or become aware of and provide the completed review.

56) Perform the required pharmacovigilance activities and interventions detailed in the agreed RMP and any agreed updates to the RMP. An RMP should be submitted at the request of Medsafe or whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important milestone being reached.

Due to the unresolved concerns and additional quality, safety and efficacy data to be provided at the time of completion of the evaluation, Medsafe is unable to recommend that this product be granted consent. It is therefore recommended that the application be referred to the Medicines Assessment Advisory Committee (MAAC) under section 22(2) of the Medicines Act 1981 for their consideration. In referring the application, it is requested that the MAAC focus on the specific aspects in their consideration of the application:

- The conditions and consent time period proposed for provisional consent under section 23 of the Medicines Act 1981. Specifically, whether these are appropriate and sufficient given the data provided up to the time of referral, as well as whether any additional conditions should be applied.

- Whether the benefit risk balance of Comirnaty vaccine for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older is positive.

- Whether to accept the proposed indications, or to request that the Sponsor update the New Zealand data sheet so that it is harmonised with the TGA approved product information, and includes the following indication:

  Comirnaty (BNT162b2 (mRNA)) COVID-19 vaccine has provisional consent for the indication below:

  > Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older.
  >
  > The use of this vaccine should be in accordance with official recommendations.
  >
  > The decision has been made on the basis of short-term efficacy and safety data. Continued approval depends on the evidence of longer-term efficacy and safety from ongoing clinical trials and post-market assessment.

Document 8

EVALUATION OF A NEW EXCIPIENT

Substance name: ALC-0315

Structure:

[redacted] s 9(2)(b)(ii)

IV.5 Evaluator's overall conclusions on clinical efficacy

With currently available data from the pivotal study, follow-up data is only available for about one to two months. Therefore there is uncertainty about how long protection will last. In addition, the number of cases of symptomatic COVID-19 in subgroups of the study population is often low. There is thus uncertainty regarding efficacy in people of Polynesian and Asian ethnicity.

The pivotal study for this application is the Phase 2/3 Study C4591001 is ongoing in the USA, Argentina, Brazil, Germany, South Africa, and Turkey with the first subject first visit on 29 April 2020.

Study participants had median age 52 ears, with about 22% 65 years of age or older. There were 76 participants (0.2%) of Native Hawaiian or other Pacific Islander ethnicity. There were 1,625 participants of Asian ethnicity. At baseline, about 21% of participants had any Charlson comorbidity (including diabetes 8% and chronic pulmonary disease 8%). At baseline, 197 subjects (0.5%) had HIV infection.

The pivotal study shows two doses the modRNA COVID-19 Vaccine (BNT162b2 30 µg) three weeks apart provide 95% protection against symptomatic COVID-19 (as at data cutoff 14 November 2020, n= 37,000 with follow-up usually about one to two months).

At the earliest, it is from April 2021 that updated efficacy estimates regarding longer duration of vaccine protection are expected to become available.

Document 10

For participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, from 7 days after the second dose, there were the following cases of symptomatic laboratory-confirmed COVID-19 of any severity;

- 8 (out of 18,198; 0.04%) in the BNT162b2 group and
- 162 (out of 18,325; 0.9%) in the placebo group.

In the placebo group, 162 instances of symptomatic COVID infection in about 2,222 person-years. Given the approximately 18,000 subjects who received placebo, surveillance time for the majority of subjects is likely to be between one to two months.

For the other co-primary efficacy endpoint, VE against confirmed COVID-19 in participants with or without evidence of SARS-CoV-2 infection was 94.6% (with 9 and 169 cases in the BNT162b2 and placebo groups respectively). In the elderly, participants ≥65 years of age with or without prior evidence of SARS-CoV-2 infection, VE was 94.7% (corresponding to 1 case in the BNT162b2 and 19 in the placebo groups).

'Severe' confirmed COVID-19 meant that subject had in addition to the confirmed Covid-19 (for example) at least; severe systemic illness (eg RR ≥30 breaths per minute); or needing high-flow oxygen, or admission to an ICU; or death. Severe disease was noted in one case of the vaccinated group and 3 cases in the placebo group. Although at this stage of the study's follow-up, only about 1% of placebo subjects have developed symptomatic COVID-19, severe disease was not common (about 2% of those with symptomatic disease had severe disease; 3 out of 162).

Some subjects who at baseline had evidence of prior COVID-19 infection, subsequently developed symptomatic COVID-19 at least 7 days after Dose 2. As noted in the VRBPAC Briefing Document, only 3% of participants had evidence of prior infection at study enrolment. These data do suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

V. [redacted] s 9(2)(b)(ii)

[redacted] (2)(b)(ii)