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24 May 2021

Andrew Lewis

By email: fyi-request-15147-e8906216@requests.fyi.org.nz
Ref: H202106023

Dear Andrew Lewis

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 13 April 2021 for COVID-19 vaccination information. A copy of your full request is enclosed. Please accept my apologies for the delay in responding to your request, which was due to an administrative oversight.

Turning to parts one, two, three, four (b) to (d), four (h) to (l), five, six, seven and eight of your request, these appear to be asking the Ministry to comment on the safety and efficacy of the COVID-19 vaccine. While the Act enables people to request official information from the Ministry, it only applies to information it holds. There is no obligation to create information in order to respond to requests, nor is the Ministry obliged to provide an opinion. The Act does not support requests in which a requester quotes information and then seeks some form of comment on it, couched as a request for official information. Therefore, I am refusing these parts of your request under section 18(g)(i) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

Regarding four (a) of your request, information on approval status of COVID-19 vaccine applications received by Medsafe is publicly available at: www.medsafe.govt.nz/COVID-19/status-of-applications.asp.

In response to parts four (e) and (f) of your request, COVID-19 vaccine information for health professionals is publicly available at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals.

Regarding part four (g) of your request, a list of ingredients is publicly available at: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf. No human cell lines are used in the manufacture of the vaccine.

In response to part nine of your request, section 4.1 of the Comirnaty data sheet states:

> *"COMIRNATY has provisional consent (see section 5.1) for the indication: 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."*

For your reference, the following links may be of interest to you:

- World Health Organization's global research on COVID-19 - www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov
- The recently updated *Immunisation Handbook,* which includes a new chapter on COVID-19 and vaccines: www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19
- COVID-19 vaccine safety and approval: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-safety-and-approval
- Guide to reporting adverse reactions: www.medsafe.govt.nz/profs/puarticles/adrreport.htm
- COVID-19 vaccine data: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-vaccine-data
- COVID-19 vaccine research insights: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-research-insights
- COVID-19 vaccine evaluation and approval process: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp

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: xxxx@xxxxxxxxx.xxxxxxxxxx.xx 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

Chris James
Group Manager
Medsafe

Copy of full request:

From: Andrew Lewis <fyi-request-15147-e8906216@requests.fyi.org.nz>
Sent: Tuesday, 13 April 2021 09:59
To: OIA Requests <oiagr@health.govt.nz>
Subject: Official Information request - Request for further information regarding SARS CoV 2 vaccination program

Dear Ministry of Health,

Freedom of information act request regarding SARS CoV2 (Covid19) immunisation program

The government is rolling out SARS CoV2 vaccine and has provided information on the government web site and through media advertising campaign.

The government clearly makes the claim that the product being offered is safe and effective.

As a concerned individual I would like more information in order to understand what is meant by safe and effective in order to make a truly informed choice regarding the product/procedure being offered by the government. With that goal in mind I respectfully request the following information to be supplied and any questions to be answered.

Any use of the word product in the following request refers to Pfizer Covid 19 vaccine and any other vaccine intended for public use against Covid 19 disease.

1.The medical procedure the government is offering in this program, is deemed to be a vaccine against the virus that causes Covid-19 disease (SARS CoV 2). Please supply references to peer reviewed scientific papers the government is relying on to support the implied claim that this product actually performs the actions of a vaccine.

A vaccine is :-

‘a substance containing a virus or bacterium in a form that is not harmful, given to a person or animal to prevent them from getting the disease that the virus or bacterium causes.' - Cambridge dictionary.

Please supply references to the peer reviewed science and any information in emails or meeting notes the government is relying on to prove that this product stops transmission of SARS CoV2 between individuals and prevents infection by SARS CoV2?

2. The government claims the product has been used ‘successfully all around the world’. Please supply the data the government is relying on to make this claim and please supply any data and/or correspondence which defines what successful means in this context.

3. Effectiveness

(a) The government is claiming 95% effectiveness for this product. Please supply references to peer reviewed science and/or correspondence with Pfizer to substantiate this claim and that shows this claim includes 95% effectiveness in stopping transmission and 95% effectiveness in preventing the recipient of the product from subsequently contracting the disease and that details how long any protection will last? Ashley Bloomfield in the video on Ministry of Health web site states that ‘our research’ indicated protection for 8 months. Please supply the ‘our research’ he is referring to. He also says the expectation is for a longer period of protection. Please supply the information on which that statement is based.

(b) Ashley Bloomfield clearly states in the video on Ministry of Health website that the vaccine may not fully protect all who receive it. Please supply any data on record (scientific reviews, emails, meeting notes etc.) that clarifies what is meant by full protection and how 'all' is quantitatively defined.

(c) The Number Needed to Treat (NNT) is a well accepted determinant of medical efficacy and cost effectiveness of a medical intervention and is defined thus:-

The Number Needed to Treat (NNT) is the number of patients you need to treat to prevent one additional bad outcome (death, stroke, etc.). For example, if a drug has an NNT of 5, it means you have to treat 5 people with the drug to prevent one additional bad outcome. More detailed discussion of the nature of the NNT measure can be found in the EBM Note on summarising the effects of therapy in the journal Evidence-Based Medicine 1997;2:103-4.
https://scanmail.trustwave.com/?c=15517&d=kML04BNxz24NTaTWbN731Nc3pmKSiqwhvP-jMQMzvQ&u=https%3a%2f%2fwww%2ecebm%2eox%2eac%2euk%2fresources%2febm-tools%2fnumber-needed-to-treat-nnt

Please supply references to peer reviewed science detailing the NNT for this product.

(d) Please provide any information (peer reviewed scientific data, emails, meeting notes etc.) on record which affirms that the product will protect not only against the current SARS CoV 2 virus but against future variants of said virus.

4. Safety

(a) The government's regulating authority, Medsafe, has approved this product. Please provide the results of Medsafe's own safety testing and any other information that proves the product has been subjected to all the normal safety trials which would ordinarily be needed to give approval for use in the New Zealand population? Please supply information the government is relying on to confirm or deny that approval in this context means emergency use authorisation.

(b) Ashley Bloomfield in his video presentation clearly states that this product has been subjected to the same high safety standards as other vaccines. Please supply any information (scientific data, emails, meeting notes etc.) on which this statement is based.

(c)The government claims this product is safe. According to the Cambridge dictionary safe means 'not dangerous or likely to cause harm'. The reality is, as we know that all medicines have side effects. Please supply information the government is relying to guarantee this product will not cause permanent harm (including death) to any recipient.

(d) The potential long term effects of this product are not known since it has not been tested long enough. Please supply any information (scientific data, emails, meeting notes etc.) which may indicate long term negative health impact of this product.

(e) Ashley Bloomfield states that before any individual is given this product a Health Care Provider will assess whether it is safe to administer to any particular individual. Please provide information which states what is meant by Health Care Provider. Please provide information which details the qualifications of a vaccinator who is not a recognised, registered health care professional.

(f) Please provide the assessment criteria the Health Care Provider/vaccinator will use to determine suitability/safety of this product for a particular individual.

(g) Please supply a list of all the ingredients in this product both active and inactive and please supply details of human cell lines used in the manufacture of this product.

(h) Please supply information (scientific data, emails, meeting notes) that clarifies whether the lipid nano-particles in this product will/will not cross the blood brain barrier.

(i) Please supply the data you have on record (peer reviewed science, emails, meeting notes other correspondence with Pfizer) that indicates the expected allergic response to poly-ethylene glycol (PEG) contained within this product.

(j) Please supply information (peer reviewed scientific data, emails, meeting notes etc) which confirm mRNA fragments in this product will not have long term genetic consequences to human biology.The government fact sheet ((https://scanmail.trustwave.com/?c=15517&d=kML04BNxz24NTaTWbN731Nc3pmKSiqwhvPjwNVYwvQ&u=https%3a%2f%2fcovid19%2egovt%2enz%2fassets%2fresources%2fVaccine-resources%2fCOVID-19-vaccine-FAQs-No-2-for-border-and-MIQ-workers%2epdf) clearly states that there is no possibility this product will affect DNA. Please supply the definitive evidence being relied on by government for that statement and that clearly shows that reverse transcriptase activity within the cell is incapable of incorporating product mRNA into human DNA.

(k) Please supply information (peer reviewed scientific data, emails, meeting notes etc) you have on record which confirms that antibody dependent enhancement which may lead to exacerbation of Covid 19 symptoms will not occur. Data from the study of SARS-CoV and other respiratory viruses suggest that anti-SARS-CoV-2 antibodies could exacerbate COVID-19 through antibody-dependent enhancement (ADE)
- https://scanmail.trustwave.com/?c=15517&d=kML04BNxz24NTaTWbN731Nc3pmKSiqwhvPigMVRh4Q&u=https%3a%2f%2fpubmed%2encbi%2enlm%2enih%2egov%2f32908214%2f

(l) Please supply information (peer reviewed scientific data, emails, meeting notes etc) which you have on record regarding the matter of viral immune escape in relation to this product.

5. Please supply information (peer reviewed scientific data, emails, meeting notes etc) that is on record which details the isolation of the virus named SARS CoV 2 .

6. If someone is already immune to SARS CoV 2, assessed by antibody titre, then provide information you have as to why they would need to take this product to protect them.

7.Please supply information the government is relying on to deny the New Zealand population the access to proven therapeutic interventions including Ivermectin, Hydroxy-chloroquine / zinc.

8.Please supply information on record the government is using to deny the New Zealand population the information necessary to maintain a strong immune function particularly the role of vitamin D in maintaining a healthy immune system.

9. The Medicines Act 1981 section 23 states that a NEW medicine (which this product is) may be given provisional use authorisation for a LIMITED number of people. Please provide the legislation which authorises the minister to override this statute and give this product to the whole population.

I thank you for your kind attention.

Yours faithfully,

Andrew Lewis

This is an Official Information request made via the FYI website.

Please use this email address for all replies to this request:
fyi-request-1xxxxxxxxxxxx@xxxxxxxx.xxx.org.nz

Is oiagr@moh.govt.nz the wrong address for Official Information requests to Ministry of Health? If so, please contact us using this form:
https://scanmail.trustwave.com/?c=15517&d=kML04BNxz24NTaTWbN731Nc3pmKSiqwhvKqiNlFk7A&u=https%3a%2f%2ffyi%2eorg%2enz%2fchange%5frequest%2fnew%3fbody%3dministry%5fof%5fhealth

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