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21 January 2022

Chuck Schooner

By email: fyi-request-17816-a5965a61@requests.fyi.org.nz
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Ref: H202117069
H202117155

Tēnā koe Chuck

Response to your request for official information

Thank you for your request of 3 December 2021 under the Official Information Act 1982 (the Act) for information about the vaccination of young people with the Pfizer Comirnaty vaccine. Your request was transferred by the Office of the Minister for COVID-19 Response to the Ministry of Health (the Ministry) for response.

On 6 December 2021, you made a further request about batch sampling of the Comirnaty vaccine, and on 8 and 10 December 2021, you asked for information related to the publication in the United States of the *Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021* document (hereafter the Cumulative Analysis Report).

Given all these requests involve COVID-19 vaccines, the Ministry has decided to consolidate them into one response to reduce the administrative burden. Rather than repeat your requests in full, they are attached as Appendix 1.

Much of your requests are not requests for official information. While the Act allows people to ask for information from Ministers, government agencies and Crown entities, there is no obligation under the Act for agencies to create new information, compile information they do not hold, provide, or prove an opinion, or respond to inflammatory statements or hypothetical questions. Much of this request seems designed to engage in the debate with the Ministry about the Government's COVID-19 vaccination and immunisation programme. The Act does not support requests where statements are put to agency for comment, couched as a request for official information. Within this category fall several statements including your references to Medsafe deciding "to inflict this poison on the next generation," "who will ultimately be responsible for potentially inflicting anyone of the following illnesses on children and why they believe this is okay," comments purportedly made to a hearing in the United States, decisions made in Japan or swine flu in the 1970s. Therefore, these parts of your request are refused under section 18(g) on the grounds that the information is not held. Please also note that the inflammatory language you have used in your requests might result in future requests being refused as vexatious under section 18(h).

Turning to your request for information about the vaccination of young people with the Comirnaty vaccine. Asking for "all documentation" brings within scope significant numbers of emails and is therefore likely to be refused under section 18(f) on the grounds that it would

involve substantial collation. However, a narrower request on the same subject is processed by the Ministry and is due to be published at: https://fyi.org.nz/request/17871-evidence-used-in-determining-whether-to-vaccinate-children-5-11 Therefore this part of your request is refused under section 18(d) of the Act on the grounds that the information requested will soon be publicly available. There is further information about vaccination of young people at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-health-advice/covid-19-vaccine-and-children-information-parents-and-caregivers.

Turning to those parts of your requests which provides a lengthy list of adverse events following immunisation (AEFI) lifted from the Cumulative Analysis Report. The Ministry and Medsafe have received several requests for information related to the Cumulative Analysis Report and its publication in the United States. A comprehensive response that explains its genesis and relevance in New Zealand, and addresses your questions has been published at: www.health.govt.nz/system/files/documents/information-release/h202117570_response_0.pdf This response also provides a comprehensive answer to your questions related to adverse events following immunisation (AEFI). Therefore, this part of your request is refused under section 18(d) because a response to the matters you have raised is publicly available.

Turning to questions about treatment with Remdesivir (and about treatment of COVID-19 in general) it is important to note that neither the Ministry nor Medsafe treats patients. Treatment is the responsibility of general practitioners and health professionals working in district health boards (DHBs). If you want further information about treatment protocols, the contact details for all DHBs are at available at: www.health.govt.nz/new-zealand-health-system/key-health-sector-organisations-and-people/district-health-boards/district-health-board-websites.

Remdesivir has not been approved by Medsafe as it is prescribed under section 25 of the Medicines Act 1981. There is more information about the funding and use of Remdesivir at: https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/decision-2021-09-16-remdesivir-to-treat-covid-19/. You may want to contact Pharmac directly for more information at: https://pharmac.govt.nz/about/contact/

Turning to your questions about quality controls and sampling of the Pfizer Comirnaty vaccine, I can advise that the quantitative formulation is submitted to Medsafe and reviewed as part of the evaluation process. The qualitative formulation is published in the Datasheet, and on Medsafe's website, and is a complete reflection of the vaccine ingredients. Information regarding the vaccine approval process can be found at: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.

The vaccine is manufactured and tested according to the requirements of Good Manufacturing Practice and the relevant sites are regularly inspected by regulators (for example, the United States Food and Drug Administration) to ensure that the quality meets these requirements. As part of Medsafe's evaluation process, the sponsor (Pfizer) must supply evidence of current Good Manufacturing Practice for manufacturing and testing sites. The sites of manufacture and testing are published at: www.medsafe.govt.nz/regulatory/ProductDetail.asp?ID=21938.

In addition, before being delivered to New Zealand, batches of the Pfizer vaccines are tested by a testing laboratory, independent of Pfizer. This independent testing has regulatory oversight, for example by way of European Union Official Control Authority Batch Release certification. The Gazette notice that outlines these requirements is available at: www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette-Oct-2021.pdf.

As the Ministry has previously told you, the Pfizer Comirnaty vaccine is not gene therapy and does not interact with a person's DNA or genes. There is more information about this at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-how-vaccine-works. Please be advised that repeatedly asking the same or

similar questions in future could result in such requests being refused under section 18(h) as frivolous or vexatious.

You have also asked about aspects of the contract or official agreement or supply agreement of the first COVID-19 vaccine purchase agreement signed by the New Zealand Government with the vaccine provider Pfizer and BioNTech. This is withheld in full under section 9(2)(b)(ii) of the Act as its release would likely unreasonably prejudice the commercial position of the person who supplied the information. However, I can confirm there are no clauses prohibiting testing of the contents of the vials as you have suggested.

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/responses-official-information-act-requests.

Nāku noa, nā

Jan Torres
Acting Manager, OIA Services
Office of the Director-General

Appendix 1

Request on 3 December 2021:

You are recently on record as saying they are assessing if this vaccine should be given to 7-11 year olds.

Please provide all documentation confirming that the vaccine is safe for 7-11 year olds. Please specifically provide a cost-benefit analysis to support jabs for this age group.

At an FDA panel hearing an expert doctor stated that the Pfizer vaccine "failed any reasonable risk-benefit calculus in connection with children. He went on to state that vaccinating this age group you are assigning innocent kids and uninformed parents to a fate that will undoubtedly rob some of them of their lives".

Please provide a generic email that I can send this Pfizer document too so that Medsafe are fully informed when they decide to inflict this poison on the next generation.

Can you please state who will ultimately be responsible for potentially inflicting anyone of the following illnesses on children and why they believe this is okay? The list below is partial only directly from a Pfizer document.

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;AntiGAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Antiinsulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothro Can you confirm if you will ultimately be responsible for the roll out in kids?

And if you are will you take any responsibility for potentially giving children anyone of the following illnesses from a recently released Pfizer document. 1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;AntiGAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Antiinsulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothro.

Request on 6 December 2021

Latest statistics shows that a large amount of the New Zealand population has been vaccinated. A lot of them have been vaccinated safely yet there are now 126,679 adverse reports that have been reported including the below very serious side effects.

- strokes
- at least one death
- cardiac arrest
- myocarditis & pericarditis
- haemmorrage

Despite all of these very serious side effects the Ministry of Health, and I say this in gest given statistics can you please state if

- Medsafe has done any batch sampling of the Pfizer vaccines to assess consistency?
- If not, why not?
- Does the Pfizer document preclude any and all testing of the contents in the vial? This is a yes no answer and does not require any sensitive information being disclosed

- Are Medsafe aware that in Japan 1.6m doses of the vaccine were discarded due to contamination - how does Medsafe determine if any of the Pfizer vaccines are contaminated?
- What quality controls are completed by Medsafe to ensure the vaccine doses are consistent and not contaminated?
- Would very serious side effects in some versus no side effects in others raise any flags at Medsafe and how would that be investigated?
- Are there clauses in the Pfizer contract that preclude any investigation of the vials at all? Yes or No
- In the 1970's 1/3 of the American population were vaccinated against swine flu - there were 26 suspicious deaths and then the vaccine was stopped. Pfizers cumulative analysis report recently released under Official Information by the FDA confirms that over 1,200 people died in the first 90 days of the Pfizer roll out directly from the vaccine (and to date thousands more globally). What has changed from the 70's versus now? Given it is now categorically known from Pfizers own documentation that this vaccine/gene therapy can kill you could any criminal charges be laid against the persons approving this vaccine if they were knowingly aware of the Pfizer cumulative analysis report?

Request on 8 December 2021

On receipt of a trove of Pfizer documents released by the FDA.

Please state if Pfizer provided the following document to Medsafe for their safety assessment.

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

If so, when did Medsafe receive this document. If not, why was this document not provided given the date. Now that Medsafe is aware of the document and the vaccine has caused death and 10 pages of other serious side effects can you honestly say proper due diligence was completed.

Request on 10 December 2021

Please state if the following report was used in the assessment to approve the Pfizer/Biontech vaccine when Medsafe first approved this gene therapy/vaccine.

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

If the report was not available can you please state if Medsafe requested any real time safety reports from Pfizer in advance of approving this gene therapy.

By the time Medsafe approved this gene therapy the vaccine had been widely used globally and so there would be real time statistics. If not, did you rely on Pfizer trial information only?

Medsafe then approved the gene therapy for two more years and stated Pfizer had met a number of safety conditions following their provisional approval. Please provide all reports/evidence that Pfizer provided Medsafe that prove that they met their safety conditions that were part of the first gazette notice.

The above report was dated early 2021 - please state if Pfizer had provided this to Medsafe at all when they have completed any of their due diligence in assessing this gene therapy.

Please state if on the release of the documents by the FDA has Medsafe requested all of the Pfizer documents that have been released - please provide a list of all the Pfizer documents that Medsafe have relied upon in approving this gene therapy.

This document is now available and if you approve this in children who will ultimately be responsible for illnesses in children? Medsafe or Ministry of Health.

Were Medsafe responsible for approving Remdesivir as a Covid-19 treatment.

Is Medsafe/Ministry of Health using Remdesivir as a Covid-19 treatment?
What studies were used to say Remdesivir was safe?

An Ebola study using Remdesivir showed that it was pulled from use in a 12 month trial after six months because it killed 54% of the trial subjects it used.

The Remdesiver study also showed that patients were having the following side effects

- 10 day treatment of Covid-19 showed 23% had serious adverse events were organ dysfunction syndrome, septic shock, acute kidney failure and kidney failure.

Please state how many Covid patients have been treated with Remdesiver in New Zealand and how many of them had the above side effects and died. It appears Remdesiver will kill you. Did Medsafe do any due diligence for Remdesiver as it will likely poison patients.