STATEMENT OF CLAIM

Dated 14 April 2021

THE PARTIES

1. The Plaintiff is a registered incorporated society, with incorporation number 50060048,having its registered office at 235 Kohaihai Road, Karamea, New Zealand.

2. The Plaintiff's rules of incorporation include at 3.1 "*to educate, empower and take all actions the Society deems appropriate by Committee, including the taking of legal action against individuals or organisations as well as promoting informed decision making and accountability in respect of health and wellbeing".*

3. The First Defendant is the Minister of Health and has statutory responsibility for the administration of the Medicines Act 1981 **("the Medicines Act"**).

4. The Second Defendant, is the Director-General of Health, and holds delegated responsibilities from the Minister of Health under the Medicines Act.

5. The Third Defendant, Christopher James is the manager of the Medicines Safety division of the Ministry of Health, which is known as "Medsafe". He holds delegated responsibilities from the Minister of Health under the Medicines Act for the granting of provisional consent and gazettal of new medicines under section 20 and 23(1) of the Medicines Act.

6. The Fourth Defendant is the Prime Minister of New Zealand, the head of the Department of Prime Minister and Cabinet and responsible for the New Zealand government's COVID-19 response, including strategy, public engagement and communications.

7. The Fifth Defendant is the Minister of COVID-19 response and has delegated authority for the Covid-19 Public Health Response Act 2020 from the fourth defendant, the Prime Minister.

8. The Sixth Defendant is the Attorney-General who is the senior law officer and who has overall responsibility for legal proceedings against the Crown including pursuant to the Crown Proceedings Act and for ensuring compliance by the Crown with the rule of law.

BACKGROUND

9. In late 2019 an infectious disease, which came to be known as "Covid-19", was first reported in Wuhan, China. It was reported as causing death to approximately 1/3 of those it infected. The public initially knew very little about Covid-19 and it was very frightening for many people.

10. From 16 January 2020 until 19 March 2020, Covid-19 was classified by Public Health England as a High Consequence Infectious Disease "HCID", alongside diseases such as Ebola Virus, Lassa Fever, Avian Influenza H7N9 and H5N1 and H5N6 and H7N7, Monkeypox, Pneumonic Plague and Severe Acute respiratory syndrome "SARS".

11. The first reported case of Covid-19 in New Zealand was on 22 February 2020.

12. From 16 March 2020, the status of COVID-19 was downgraded from a HCID by Public Health UK, due inter alia to more information about mortality rates (low overall), and greater clinical awareness.

13. Throughout 2020 the New Zealand government published a series of strategies, policies, emergency legislation and orders, intended to direct and support the NZ government's evolving response to Covid-19.

14. The initial NZ government strategy was to "flatten the curve", in order to avoid overloading hospitals, intensive care facilities and the demand on ventilators.

15. On or about 8 May 2020 the NZ Government strategy changed from "flattening the curve" a strategy of "eliminating" Covid-19 from New Zealand.

16. In or about May 2020 the fourth defendant announced Covid-19 had been eliminated from New Zealand. Since May 2020, most reported cases of COVID-19 have been people who tested positive in a “PCR test” at MIQ quarantine facilities after travelling from overseas or people traced to them.

17. By 1 April 2021 there had been 2112 reported cases of Covid in New Zealand and 26 deaths with Covid. Since 30 May 2020 there have been only four deaths with Covid in New Zealand and Covid-19 remains officially eliminated in New Zealand.

THE COVID VACCINE PROGRAM

18. From mid-2020 representatives of the government, including the Prime Minister of New Zealand and Minister of COVID, publicly announced on various occasions that New Zealand was participating in an international COVID-19 vaccine development programme.

19. Vaccine development appears to have been the main focus of New Zealand’s COVID-19 exit strategy. There has been very little public comment by the government about other more orthodox ways of enhancing immunity to protect against COVID-19, for example with vitamin D, zinc, vitamin B, vitamin C or by repurposing of other approved medicines such as Ivermectin, steroids and other anti-inflammatory medications. This is despite reports overseas and published research that many of these are effective to prevent or manage COVID-19.

20. In September 2020 the Minister of Finance approved an indemnity by the New Zealand government to protect Pfizer the promoter of the new Pfizer COVID-19 vaccine, against any claims.

21. In October 2020 the fourth defendant announced the NZ government would be purchasing the Pfizer/BioNTec 162 (Comirnaty) vaccine with the (“the Pfizer mRNA vaccine”).

22. On 17 December 2020 the Prime Minister and Ministers of Science, Covid and Health jointly announced inter alia:

a. two new vaccines had been secured for New Zealand,
b. 15 million vaccines had been pre-ordered for New Zealand, enough for every New Zealander;
c. Medsafe processes for approving these vaccines had been streamlined for timeliness; and
d. readiness for the largest ever immunisation progress was progressing well and systems were on track to deliver first vaccines to border workers in the 2nd quarter of 2021 with vaccination of general population in the second half of the year.

23. On 1 February 2021 Medsafe published an agenda for the 109th meeting of the Medicines Assessment Advisory Committee, to be held on 2 February 2021. Item 4.1 of this agenda is headed

"Applications for consent to distribute a new medicine under section 20/23/24 of the Medicines Act 1981 (referred by the Minister of Health under section 22(2).

Agenda at 4.1: *"Comirnaty (COVID-19 mRNA vaccine), 0.5 mg/mL (TT50-10853) Pfizer New Zealand Limited.*

This product is a prescription medicine proposed for prevention of COVID-19 disease caused by SARS-CoV-2 in adults and adolescents from 16 years of age and older.

Comirnaty is a new vaccine employing novel technology (mRNA) and works by triggering the immune system to protect against COVID-19 disease…."

24. On 3 February the third defendant published a Gazette notice ("the Gazette notice"), under delegated authority from the first defendant, advising of "Provisional Consent to the Distribution of a New Medicine" for Comirnaty COVID-19 mRNA vaccine" ("the Pfizer mRNA vaccine") pursuant of s23(1) of the Medicines Act 1981.

25. The Gazette notice stated inter alia:

a. Provisional consent was granted for nine months to address an urgent clinical need;

b. The active ingredient is BNT162b2 [mRNA] 0/5mg/ml;

c. The New Zealand sponsor was Pfizer New Zealand Ltd;

d. The provisional consent was given subject to the New Zealand sponsor fulfilling 58 obligations within specified dates between February and July 2021;

e. The obligations required various information including certification, data, analysis, reassessment, active substance process validation, descriptions of technology, discussion of results, additional data to demonstrate the purity of S1 and S2 proteins generated by the process, active substance and finished product specifications including for different batches, review of specifications for mRNA integrity, evaluation of impurities, validation of upscaling from laboratory to commercial facilities, verification of testing methods and an array of other analysis and process verification information relevant to the safety, efficacy and integrity of the new medicines.

25. The Gazette notice did not state:

a) that the Pfizer vaccine was a prescription only medicine, and

b) did not state which categories of people were within the “limited number of patients” anticipated by a s23(1) provisional consent.

26. On 10 February 2021 the fifth defendant announced Cabinet approval for the Pfizer mRNA vaccine to be administered to everyone in New Zealand aged 16 years and older. There was no reference to the section 23(1) provisional consent being only for treatment of a limited number of patients.

27. From on or about 8 March 2021 the government developed a communications strategy with internal and external communications advisors, and published a series of advertisements on www.beehive.govt.nz and on media including TV, radio and newspapers and social media (“the Pfizer vaccine advertisements”).

28. The Pfizer vaccine advertisements referred to a four staged COVID-19 "vaccination rollout plan" to everyone in the New Zealand over 16. This includes healthy New Zealanders and people who are at little risk of exposure to COVID-19, and people who due to their age and state of health are unlikely to suffer any significant adverse effects in the event they became exposed to COVID-19.

Particulars:

New Zealand's vaccination rollout plan

The rollout plan for the Pfizer vaccine is simple. Everyone in the Country aged 16 and over falls into one of four groups. Firstly we'll protect those most at risk of picking up the virus in their workplace- and then those most at risk of getting seriously ill or dying form COVID-19.

NOW	*FROM MARCH*	*FROM MAY*	*FROM JULY*
Group 1	*Group 2*	*Group 3*	*Group 4*
Border and MIQ workers	*Frontline….*	*65+ and people with underlying health conditions*	*Everyone else*

More strength. More freedom. More options
We'll let you know when it's your turn for the vaccine. Until then please keep using the NZ COVID-19 tracer app, and stay home if you are sick.
Covid19.govt.nz/vaccine
Unite against COVID-19
New Zealand government

More strength. More freedom. More options
We'll let you know when it's your turn for the vaccine. Until then please keep using the NZ COVID-19 tracer app and stay home if you are sick.
covid19.govt.nz/vaccine
Unite against COVID-19
New Zealand government

28. The advertisements for the vaccination rollout plan included the following representations in a national media campaign, including in The Press and many other newspapers on or about Saturday 13 March 2021:

"Any vaccine's strength is in numbers. The more of us who get vaccinated the stronger and safer we'll all be.

It will give us more freedom in our daily lives, and more options for our whanau, our businesses and our country. Because when we roll up our sleeves, we're helping to protect all of us.

Here are the key facts about the Pfizer vaccine:

It's safe
It has been approved by our own Medsafe experts. Its also already been used successfully all around the world by millions of people, and by thousands here in New Zealand too.

Its effective
The Pfizer vaccine is 95% effective when you receive both doses

It's free
The vaccine will be free for everyone in New Zealand. We have secured over 10 million doses of the Pfizer vaccine. That's enough for all of New Zealand."

29. Since then, the Second, Fourth and Fifth Defendants and other Ministers of the Crown including the Associate Minister of Helath/Minister for Pacific Peoples Hon Aupito William Sio and the Minister for Seniors Dr Ayesha Verrall (who are both represented by the Seventh Defendant) have made numerous claims that:
    a) the Pfizer vaccine is "safe and effective",
    b) the Pfizer vaccine is approved by Medsafe and
    c) the Medsafe approval means the Pfizer vaccine is safe.

30. In fact, the Pfizer vaccine has only been granted "provisional consent" under Section 23(1) of the Medicines Act 1981 which provides for approval only where the Minister is of the opinion that it is desirable that the medicine be sold, supplied or used "on a restricted basis for the treatment of a limited number of patients".

31. The statutory scheme of the Medicines Act generally requires extensive testing of new medicines before they can be sold, supplied or distributed. Section 23(1) provides an exception which allows "provisional consent" to be given where clinical trials and other safety testing is not complete, but only for restricted treatment of a limited number of patients.

FIRST CAUSE OF ACTION: BREACH OF THE MEDICINES ACT 1981- First, second, third and sixth defendants

32. The plaintiff repeats paragraphs 1 to 31 of this Statement of Claim and says the New Zealand vaccination rollout plan is unlawful and in breach of the s23(1) provisional consent because injecting "everyone in the country aged 16 and over" is not "the "treatment of a limited number of patients":

a. The vaccination rollout plan proposes to inject everyone in the country aged 16 and over, including:

   i. People who are healthy and have strong immunity;

   ii. People who already have antibodies to COVID-19 from prior exposure;

   iii. People who have medical conditions which may expose them to particular risks fromthe Pfizer mRNA vaccine;

   iv. People who are pregnant or breastfeeding;

   v. People who are on medications which have not been tested in conjunction with thePfizer mRNA vaccine;

   vi. People with a history of allergies or anaphylactic shock reactions to ingredients in the Pfizer vaccine or other medicines;

   vii. People who oppose the vaccine on ethical or religious grounds;

   viii. People who are not in a risk group for COVID-19;

   ix. People who would prefer to self-isolate than be exposed to this novel mRNAvaccine.

b. Further the New Zealand vaccination rollout plan fails to recognise or consider:

i. There are other safe and established methods of protecting against and treating forCOVID-19;
ii. COVID-19 is claimed by the defendant's to be eliminated from New Zealand;
iii. New Zealand already has effective measures in place to manage COVID-19.

WHEREFORE THE PLAINTIFF SEEKS:

a. A declaration that the New Zealand vaccination rollout plan is unlawful and in breach of the s23(1) Provisional Consent because the injection of "everyone in New Zealand aged 16 and over" is not "the treatment of a limited number of patients".

b. An order directing the Government to stay the vaccination rollout plan.

c. An order directing the First and Second Defendants to enforce section 23(1) in relation tothe Pfizer vaccine and the vaccination rollout plan.

d. Costs.

AND BY WAY OF A SECOND CAUSE OF ACTION: JUDICIAL REVIEW- First second, third and sixth defendants

The Plaintiff repeats paragraphs 1 to 31 of this Statement of Claim and further says:

33. The Medicines Act provides for the classification of medicines as prescription, restricted (pharmacists-only) medicines or pharmacy-only medicines, based on the risk profile of the medicine and the extent of medical overview required for its safeuse.

34. By way of comparison the annual influenza vaccination is a prescription only medicine.

35. On 1 February 2021 the agenda presented by the third defendant on behalf of the first defendant for the application to the 109th meeting of the Medicines Advisory Committee ("MAAC") to be held on 2 February 2021, seeks advice on the approval of the Pfizer vaccine as a prescription only medicine.

36. The Gazette notice for the Pfizer vaccine dated 3 February which followed from that advice omits any reference to the provisional consent being on a prescription only basis.

37. No evidence is publicly available to explain if the omission of the "prescription" classification was by error, or if a decision was made to omit this and any other restrictions on use. To date the defendants have failed to answer the plaintiff's questions about this, which were set out in an OPEN LETTER dated 31 March 2021 from the Plaintiff's lawyer Sue Grey to each of the defendants or provide any reasons for this omission.

38. The omission means that this novel medicine with only provisional consent can be injected by people including people who have completed a brief "vaccinator" course but have no medical training and who are unqualified to give medical advice on questions that are important for informed decision making and which may affect the safety and welfare of recipients.

39. The plaintiff seeks judicial review of the decision of the first and third defendant to purport to grant provisional consent under s23(1) of the Medicines Act for this novel medicine was unlawful, unreasonable and/or irrational:

40. Particulars:

a) Failure to identify the criteria for assessing the limited number of patients may be prescribed the Pfizer vaccine;
b) Failure to ensure the vaccine rollout plan limited the rollout in accordance with the intent of s23(1)
c) Failure to require compliance with the 58 conditions of the provisional consent before rollout of the Pfizer vaccine;

d) Failure to require completion of Stage 1,2 and 3 clinical trials to assess safety and effectiveness before rollout of the Pfizer vaccine;
e) Failure to impose a “prescription only” classification;
f) Failure to undertake any risk/benefit assessment for different categories of patients, or people with different medical conditions;
g) Relying on Emergency Approvals of the Pfizer vaccine in other countries where COVID-19 is not eliminated and which accordingly which have a different risk profile than New Zealand.
h) Promoting a regime which allows the Pfizer vaccine to be injected by employees, agents and/or contractors who have no medical training and who are unable to give medical advice on the safety or otherwise for patients with different medical conditions and without informed consent.

WHEREFORE THE PLAINTIFF SEEKS:

A. A direction that the decision of the First and Third Defendants as set out in the Gazette notice dated 3 February 2021 must be set aside and a direction that the application be reconsidered pursuant to the purpose of the Medicine Act, the statutory scheme and section 23(1) of the Medicines Act.

B. An order directing the Government to stay the vaccination rollout plan until the reconsideration in (A) above is completed;

C. Costs.

AND BY WAY OF A THIRD CAUSE OF ACTION: BREACH OF THE FAIR TRADING ACT 1986- All defendants

The Plaintiff repeats paragraphs 1 to 31 of this Statement of Claim and further says:

41. All the defendants are ‘in trade” due to the purchase of the Pfizer vaccines, providing an indemnity for any harm caused by the Pfizer vaccines, and the engagement of public relations consultants to develop “Unite against COVID-19” advice sheets, a media campaign, and promotion and

advertising of the Pfizer vaccines widely in newspapers, radio and other media.

42. By their actions, including the representations referred to in the advertisements set out in paragraph 28 of this claim and in the following particulars, the Second, Fourth, Fifth and Sixth Defendants, in promoting the vaccine rollout plan and the uptake of the Pfizer vaccine, have engaged in conduct which is misleading or deceptive, or likely to mislead or deceive:

43. Particulars of misleading and deceptive representations based on representation set out in paragraph 28 of this claim:

a. In breach of s20(3) of the Medicines Act:

i. Claiming in a Ministry of Health document headed “Getting your COVID-19 vaccine: what to expect” states: “Safety - Medsafe only grants consent for a vaccine to be used in New Zealand once they are satisfied its safe and effective enough to use”;

b. In relation to the claim the vaccine is safe:

i. The Pfizer vaccine has only provisional consent for use subject to s23(1) ofthe Medicines Act, and does not have approval by Medsafe;

ii. The Medicines Act at Section 20(3) states “No consent given under this section shall be deemed to warrant the safety or efficacy of the medicine to which the consent relates”;

iii. The Pfizer vaccine does not have FDA approval;

iv. The clinical trials for the Pfizer vaccine are not due for completion until 2023;

v. The focus in the limited initial stage 1 and 2 clinical trials on healthy people;

vi. The lack of any coherent research of the effect on or risks for use on elderly or immuno-compromised people, pregnant women or people using medications;

vii. The lack of research or analysis on the pharmokinetics or pharmodynamics to explain which parts of the body may be affected by the injected mRNA, different side effects which may be experienced, how long it continues to make Spike protein in different individuals or different parts of the body; or the breakdown products of the mRNA;

viii. The lack of research on the effects if mRNA is damaged or contaminated during production, transportation or preparation for injection, including by temperature changes or by excessive shaking;

ix. The absence of evidence that the 58 questions asked by Medsafe have been satisfactorily answered or those answers have been analysed to ensure that the concept, manufacture and production and rollout of the Pfizer vaccine is safe;

x. The documentation proved by the importer Pfizer NZ Ltd to Medsafe and published on Medsafe's website identifies considerable further research which is required to better assess safety;

xi. The VAERS register of vaccine Adverse effects Reports administered by the US government includes reference to many thousands of reports of deaths and serious and less serious adverse effects reported after receipt of the Pfizer "Comirnaty" vaccine.

c. Particulars in relation to the representation that the vaccine is effective:

i. A Ministry of Health document headed "Getting your COVID-19 vaccine: what to expect" states that "We don't yet know if it [the Pfizer vaccine] will stop you from catching or passing on the virus".

ii. The absence of evidence of how long any protection will last and how often follow up vaccines will be required.

WHEREFORE THE PLAINTIFF SEEKS

A. Interim and/or final orders directing that the Defendants cease making any further misleading and deceptive claims;

B. An order directing the Defendants to issue a corrective statements;

C. An order that the Defendants deliver up for destruction on oath all materials featuring advertising as aforementioned.

D. Costs.

AND BY WAY OF A FOURTH CAUSE OF ACTION: BREACH OF THE NEW ZEALAND BILL OF RIGHTS ACT 1990- All defendnats

The Plaintiff repeats the foregoing and further says:

44. All the defendants are bound by the NZ Bill of Rights Act.

45. The purpose of the New Zealand Bill of Rights Act 1990 ("**NZBORA"**) is to affirm New Zealand's commitment to protect and promote human rights and fundamental freedoms and to affirm New Zealand's commitment to the International Covenant on Civil and Political Rights 1966.

46. NZBORA at section 10, confirms everyone has the right not to be subjected to medical or scientific experimentation.

47. NZBORA at section 11 confirms everyone has the right to refuse medical treatment.

48. NZBORA at section 13 conforms everyone has the right to freedom of thought, conscience, religion and belief and to hold opinions without interference.

49. The Government campaign:

    a) promotes the vaccination of all New Zealanders aged 16 and over with the experimental Pfizer vaccine;

b) represents that it is the single source of truth;

c) seeks to close down alternative views which challenge the necessity or safety orefficacy of the Pfizer vaccine;

d) pressures employees to accept this vaccination under threat of loss of their employment or income;

50. The Government campaign is in breach of sections 10, 11 and 13 of the NZBORA.

WHEREFORE THE PLAINTIFF SEEKS:

A. An Order directing that the Government's vaccination rollout plan breaches the New Zealand Bill of Rights Act 1990.
B. An order directing the Defendants to issue a corrective statement.
C. A public apology on national television at the time of the usual press briefing.
D. Costs

AND BY WAY OF A FIFTH CAUSE OF ACTION: BREACH OF THE HEALTH AND DISABILITY COMMISSIONER ACT 1994 against the Sixth Defendant

The Plaintiff repeats paragraphs 1 to 31 of this Statement of Claim and further says:

51. The Code of Health and Disability Services Consumers' Rights **('the Code")** is a regulation made pursuant to the Health and Disability Commissoner Act 1994.

52. The Code specifies the duties and rights of health consumers and health providers. These rights include inter alia:

Right 5: Right to Effective communication
Right 6: Right to be fully informed
Right 7: Right to make an informed choice and give informed consent

53. The training of many vaccinators and the information provided by the defendants to vaccinators is inadequate for them to provide prospective vaccinees with sufficient information to ensure compliance with the rights protected under the Code.

WHEREFORE THE PLAINTIFF SEEKS:

A. A declaration that the vaccine plan, the approval of vaccinators who are not medically trained and the information provided by or on behalf of the Crown to prospective recipients of the Pfizer vaccine are adequate to ensure informed consent and accordingly in breach of the Code.

B. An order directing the defendants to issue corrective statements.

C. Costs

THIS STATEMENT OF CLAIM IS FILED BY:

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