COMPLAINT NUMBER	21/330 Appeal 21/014
ADVERTISER	Department of the Prime Minister and Cabinet
ADVERTISEMENT	Unite Against COVID-19, Print
DATE OF MEETING	8 March 2021
OUTCOME	Not Upheld No Further Action Required

Summary of the Complaints Board Decision
The Complaints Board did not uphold a complaint about a newspaper advertisement from the New Zealand Government answering questions about the Pfizer vaccine. The Complaints Board said while the Complainant raised a technical point in relation to the advertisement's use of the 95% figure, the likely takeout for most consumers that the vaccine will reduce the risk of you getting seriously ill from COVID-19 was not materially affected and Board agreed the advertisement was not misleading.

Advertisement
The New Zealand Government print advertisement which ran in the New Zealand Herald newspaper is titled "Answers to your COVID-19 vaccine questions". The full-page advertisement provides answers to three questions about the vaccine rollout, the side effects of the vaccine and its effectiveness. One of the questions says, "How effective is the vaccine and what does 95% mean?" The advertisement answers this by stating "Studies have shown that 95% of people who receive both doses of the vaccine were protected against getting seriouly ill." At the bottom of the page, there is a URL where people can find more information as well as the New Zealand government and "Unite Against Covid-19" logos.

Summary of the Complaint
The Complainant was concerned the Advertiser mischaracterises the 95% value used in the advertisement in relation to two different measurements applied to vaccines; relative risk reduction (RRR) and absolute risk reduction (ARR). The Complainant said the claim that the 95% (vaccine efficacy) value relates to cases of serious illness is not supported by the results of the Pfizer-BioNTech trial. The Complainant said that based on the list of symptoms, the 95% value relates to non-serious illness only.

Issues Raised:
- Truthful Presentation
- Advocacy Advertising

ASA Chair's Ruling and Appeal
The Chair of the Advertising Standards Authority (ASA) Complaints Board ruled the complaint had no grounds to proceed. The Complainant appealed the ruling and the Chairperson of the Appeal Board said that on balance the appeal application had met the threshold to establish grounds for appeal under Ground (c), evidence provided has been misinterpreted to the extent that it has affected the decision.

Summary of the Advertiser's Response

The Advertiser said the advertisement was a reasonable reflection of the evidence at the time and the effectiveness of the vaccine has continued to emerge over the course of the pandemic. The Advertiser provided examples of clinical trials. The Advertiser said vaccine protection against severe disease has been demonstrated to be generally higher than against mild disease.

When asked by the ASA whether the Advertiser considered the statement to accurately reflect the clinical trial data it provided the Pfizer data sheet and confirmed it considered the likely consumer takeout would be that the vaccine is highly effective in protecting people from getting seriously ill from COVID-19.

Relevant ASA Codes of Practice

The Chair directed the Complaints Board to consider the complaint with reference to the following codes:

ADVERTISING STANDARDS CODE

> **Principle 2: Truthful Presentation:** Advertisements must be truthful, balanced and not misleading.
>
> **Rule 2(b) Truthful Presentation:** Advertisements must not mislead or be likely to mislead, deceive or confuse consumers, abuse their trust or exploit their lack of knowledge. This includes by implication, inaccuracy, ambiguity, exaggeration, unrealistic claim, omission, false representation or otherwise. Obvious hyperbole identifiable as such is not considered to be misleading.
>
> **Rule 2(e) Advocacy advertising:** Advocacy advertising must clearly state the identity and position of the advertiser. Opinion in support of the advertiser's position must be clearly distinguishable from factual information. Factual information must be able to be substantiated.

The Advocacy Principles developed by the Complaints Board in previous decisions considered under Rule 11 of the Code of Ethics remain relevant. They say:

1. That section 14 of the New Zealand Bill of Rights Act 1990, in granting the right of freedom of expression, allows advertisers to impart information and opinions but that in exercising that right what was factual information and what was opinion, should be clearly distinguishable.

2. That the right of freedom of expression as stated in section 14 is not absolute as there could be an infringement of other people's rights. Care should be taken to ensure that this does not occur.

3. That the Codes fetter the rights granted by section 14 to ensure there is fair play between all parties on controversial issues. Therefore, in advocacy advertising and particularly on political matters the spirit of the Code is more important than technical breaches. People have the right to express their views and this right should not be unduly or unreasonably restricted by Rules.

4. That robust debate in a democratic society is to be encouraged by the media and advertisers and that the Codes should be interpreted liberally to ensure fair play by the contestants.

5. That it is essential in all advocacy advertisements that the identity of the advertiser is clear.

Relevant precedent decisions
In considering these complaints the Complaints Board referred to two precedent decisions, Decision 21/218 which was ruled No Grounds to Proceed and 21/229, which was Settled.

The full versions of these decisions can be found on the ASA website:
https://www.asa.co.nz/decisions/

Decision 21/218 concerned a brochure advertisement from the New Zealand Government about the Pfizer vaccine and the staged vaccination roll out in New Zealand. The Complainants raised a number of issues about claims made in the advertisement.

The Chair of the Complaints Board said issues related to the efficacy of the vaccine were not a matter for the ASA. The vaccine referred to in the advertising had received approval from Medsafe, the Government regulator for prescription medicines. The Chair noted the Datasheet which sets out all the relevant information for the vaccine, under Medsafe's approval process is available on the Medsafe website. The Chair consider how the average consumer would interpret language used such as "protected" and said the takeout would be the defence the vaccination can offer rather than absolute protection. The Chair ruled there were no grounds for the complaints to proceed.

Decision 21/229 concerned a print advertisement from the New Zealand Government about the Pfizer vaccine which said the vaccine was "up to 95% effective at stopping you catching COVID-19."

The Chair of the Complaints Board accepted the complaints and the Advertiser responded to confirm there had been an error in the advertisement copy and amended the statement in future advertisements to read "Studies have shown that 95% of people who receive both doses of the vaccine are protected against getting seriously ill." The Chair ruled that the self-regulatory action of amending the advertisement meant that the matter was settled.

Complaints Board Discussion

Preliminary matter
The Chair noted this complaint related to an advertisement published in the New Zealand Herald on 30/05/2021. The Chair acknowledged the delays in hearing the complaint. In part this was because the initial ruling was No Grounds to Proceed and following a successful appeal of that ruling, an Appeal Ruling was published, and parties were asked to respond to matters raised in both the complaint and the appeal submission. In addition, due to the technical nature of the complaint, the ASA requested a further response from the Advertiser. The hearing had also been impacted by the Christmas / New Year office closure.

The Chair reminded the Complaints Board to consider the content of the advertisement in the context of when it was published, in May 2021.

Complaints Board role
The Chair noted that the Complaints Board's role was to consider whether there had been a breach of the Advertising Standards Code. In deciding whether the Code has been breached the Complaints Board has regard to all relevant matters including:

- Generally prevailing community standards
- Previous decisions

- The consumer takeout of the advertisement, and
- The context, medium, audience and the product or service being advertised, which in this case is:
    - Context: The Government's response to the global pandemic
    - Medium: New Zealand Herald newspaper advertisement
    - Audience: Readership of the New Zealand Herald
    - Product: Advocacy advertising for the COVID-19 vaccination campaign

Role when considering an advocacy advertisement.
The Complaints Board noted its role is to consider the likely consumer takeout of an advertisement and complaints about advocacy advertising are considered differently to complaints about advertising for products and services.

The Complaints Board observed that in a free and democratic society, issues should be openly debated without undue hindrance or interference from authorities such as the ASA, and it should not unduly restrict the Government's role in communicating public health information to the public.

The Complaints Board also noted the Guidance Note on Advocacy Advertising states in part:

- The role of the Complaints Board in advocacy advertisements is to ensure there is fair play and the right of free expression is not unduly restricted. Accordingly, the Complaints Board liberally interprets the Codes and tries not to be concerned with minor or technical breaches.

Under Rule 2(e) Advocacy advertising of the Advertising Standards Code:
- The identity of the advertiser must be clear.
- Opinion must be clearly distinguishable from factual information, and
- Factual information must be able to be substantiated.

If the identity and position of the Advertiser is clear, a more liberal interpretation of the Advertising Standards Code is allowed.

Matters to consider in Complaints Board Deliberation
In reviewing the complaint and appeal about this advertisement, the Complaints Board took into account the role of advocacy advertising, the liberal interpretation of the Codes required by the Advocacy Principles, the application of *Electoral Commission v Cameron* [1997] 2 NZLR 421, the likely consumer takeout, and the context for the advertising; the New Zealand Government's response to the COVID-19 pandemic with an audience of all New Zealanders. The Complaints Board noted the large amount of information available from a variety of sources about COVID-19, including the Government, the science community, news media and interest groups. The Board agreed the rapidly evolving nature of the pandemic also meant information used to support statements for and against published studies could quickly become out-of-date.

Is the identity and position of the Advertiser clear?
The Complaints Board confirmed the identity and position of the Advertiser was clear. The newspaper advertisement contains the New Zealand Government logo together with the Unite against COVID-19 logo used throughout the pandemic response. The advertisement also contains a website to find out more information at covid19.govt.nz. The position of the Advertiser was also clear. The advertisement's purpose is to answer frequently asked vaccine questions and encourage people to get vaccinated. The Complaints Board said the advertisement complied with the identity requirements of Rule 2(e) of the Advertising Standards Code.

Consumer Takeout
The Complaints Board agreed the likely consumer takeout of the advertisement would be the Government was providing information to answer questions about the Pfizer vaccine. The Board also agreed a more specific takeout of the advertisement was that studies have shown that two doses of the vaccine will be highly effective at stopping you becoming seriously ill and will mean you are less likely to transmit the virus to others.

The Complaints Board considered the two elements of the statement challenged by the Complainant:

"Studies have shown that 95% of people who receive both doses of the vaccine were protected against getting seriously ill"

Is the reference to 95% in the advertisement likely to mislead or deceive or confuse consumers?
The Complaints Board agreed the advertisement was not likely to mislead or deceive the average consumer. The Complaints Board said the Advertiser was communicating information to the general public in an accessible way through a frequently asked questions format, in a newspaper advertisement.

The Board's role was to consider whether the threshold to breach Principle 2 and Rule 2(b) of the Advertising Standards Code had been met.

In making this determination the Board considered the context of an advocacy advertisement from an expert body during a global pandemic which has been declared a public health issue of international concern by the World Health Organisation.

The Complaints Board acknowledged the Complainant had raised a technical point about differentiating between relative and absolute risk reduction in the data supporting the statement in the advertisement. The Board noted the Complainant's view that a statement which more accurately aligned with the clinical data available at the time would be that *95% fewer people became ill after receiving two doses of the vaccine*.

The Complaints Board agreed the Complainant's issue was not material for consumers reading the print advertisement. The Board re-iterated the likely consumer takeout that being vaccinated will reduce the risk of getting seriously ill from COVID-19 and it did not consider the advertisement was likely to mislead or deceive consumers.

Is the claim that the vaccine's 95% (efficacy value) protection against serious illness misleading?
The Complaints Board noted the Complainant believes the 95% value relates to non-serious illness based on the symptoms listed in the case definition of a confirmed COVID-19 case in the Pfizer-BioNTech trial.

The Board confirmed the term “non-serious” is not referred to in the advertisement or the information about the trial; it appears to be the Complainant’s interpretation. The Complaints Board noted the trial also provided a case definition of ‘severe Covid’ but the advertisement does not claim 95% protection from severe Covid, only ‘against serious illness’.

In its response to this matter, the Advertiser referred the Board to the datasheet for the Pfizer vaccine: https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf

The Complaints Board noted the reference to symptoms of illness included fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhoea; vomiting. The Complaints Board agreed these symptoms by themselves or in combination with each other could result in a ‘serious illness’ for individuals. The Complaints Board agreed that for the purposes of communicating with the general public in the print advertisement in the New Zealand Herald, the reference to “serious illness” did not meet the threshold to be misleading. The Complaints Board also reiterated the advertisement was from the New Zealand Government and noted the agencies supporting the Government’s COVID-19 approach included the Department for the Prime Minister and Cabinet, the Ministry of Health and Medsafe. The role and jurisdiction of the ASA in advertising from expert bodies was addressed in *Cameron*. In accordance with the findings of the Court of Appeal, the Advertising Standards Authority was required to “tread carefully” and ensure that it did not substitute its opinion for that of the expert body, in this case, the Ministry of Health and Medsafe, with responsibility for regulating therapeutic products.

The Complaints Board unanimously agreed the statement in the advertisement had not met the threshold to mislead consumers, taking into account context, medium, audience and product and when viewed through an advocacy lens. The Complaints Board said the advertisement was not in breach of breach Principle 2 and Rule 2(b) of the Advertising Standards Code.

Outcome
The Complaints Board ruled the complaint was **Not Upheld.**

No further action required.

APPEAL INFORMATION

According to the procedures of the Advertising Standards Complaints Board, all decisions are able to be appealed by any party to the complaint. Information on our Appeal process is on our website, www.asa.co.nz. Appeals must be made in writing with notification of the intent to appeal lodged within 14 calendar days of receipt of the written decision. The substantive appeal application must be lodged with the ASA within 21 calendar days of receipt of the written decision.

APPENDICES

1. **Original Complaint**
2. **No Grounds to Proceed Ruling from Chair of the Complaints Board**
3. **Appeal Submission from Complainant**
4. **Appeal Accept Ruling from Chairperson of the Appeal Board**
5. **Initial Response from Advertiser**
6. **Additional Questions sent to Advertiser**
7. **Additional Response from Advertiser and Medsafe**

Appendix 1

ORIGINAL COMPLAINT
The advertisement states "Studies have shown that 95% of people who received both doses of the vaccine were protected against getting seriously ill.". That is simply untrue. The Pfizer study actually showed that there was a 95% relative reduction in risk of symptomatic infection, not that the vaccine protected 95% of the people who received it from getting seriously ill. in fact, as explained in the below New York Times article, the infection risk in the vaccinated group was less than 1% (actually 0.04%), but so was the infection risk in the unvaccinated group (only 0.74%). So this advertisement incorrectly explains the meaning of the much bandied-about 95% Efficacy figure for the Pfizer vaccine. But furthermore, even if the advertisement had correctly explained what an efficacy of 95% actually means in terms of risk of 2 infection, it should have been balanced by also disclosing that the unvaccinated group in the trial was at a less than 1% risk of infection.
https://www.nytimes.com/2020/12/13/learning/whatdoes-95-effective-mean-teaching-the-math-of-vaccineefficacy.html

Appendix 2

The Chair ruled there were no grounds for the complaint to proceed.

The Chair noted the Complainant considered the use of the 95% figure quoted in the advertisement to be misleading.

The Chair carefully reviewed the advertisement and noted the use of the 95% figure had been raised in a precedent Decision, 21/229. That complaint had been settled by the Chair of the Complaints Board as the Advertiser confirmed an error had been made about the use of that figure in that advertisement.

The response from the Advertiser in Decision 21/229 said in part:

> "By way of background, after advertising in press on 1st and 2nd of May, it was brought to our attention that the statement / message in question was not correct when it stated that the vaccine was "95% effective at stopping you from **catching COVID-19**" (emphasis added). Rather, studies have shown that 95% of people who received both doses of the vaccine were protected against **getting seriously ill** (Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine and BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Mass Vaccination Setting).

Turning to the complaint before her, the Chair said the Advertiser had provided links to two studies which supported the claim that 95% of people who received both doses of the vaccine were protected against getting seriously ill."

She noted the following quotes:

"A two-dose regimen of BNT262b2 conferred 95% protection against COVID-19"
(Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine
https://www.nejm.org/doi/full/10.1056/nejmoa2034577

"This study estimates a high effectiveness of the vaccine for preventing symptomatic COVID-19 in a non-controlled setting… Our study also suggest that effectiveness is high for the more serious outcomes: hospitalisation severe illness and death."
BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Mass Vaccination Setting
https://www.nejm.org/doi/full/10.1056/nejmoa2101765

The Chair said the Advertiser had provided sufficient substantiation to support the claim made about the Pfizer vaccine providing most people protection from serious illness.

The Chair said the advocacy advertisement was unlikely to mislead or deceive consumers and was not in breach Principle 2 or Rules 2(b) or 2(e) of the Advertising Standards Code.

The Chair ruled there were no grounds for the complaint to proceed.

Chair's Ruling: Complaint **No Grounds to Proceed**

Appendix 3

APPEAL FROM COMPLAINANT

The Advertisement in question stated:

> *"Studies have shown that 95% of people who received both doses of the vaccine were protected against getting seriously ill".*

The Decision referred to an earlier, precedent decision (21/229), in which the Advertiser admitted that advertising wording "95% effective at stopping you from catching COVID-19" was not correct and "Rather, studies have shown that 95% of people who received both doses of the vaccine were protected against getting seriously ill".

It is noted that the Advertisement currently in question may actually be the wording that the Advertiser settled on in response to the Decision in Complaint 21/229.

This Appeal is made on the basis that, at the very least, evidence provided to the Complaints Board has been misinterpreted to the extent it has affected the decision (i.e., at least ground (c).

Firstly, the Decision states "The Chair noted the Complainant considered the use of the 95% figure quoted in the advertisement to be misleading". That is a misinterpretation or misunderstanding of my complaint. As I originally explained, the "95% figure" (i.e., the vaccine efficacy value) is not itself in dispute. What was disputed was how the advertisement characterised that 95% value.

The only way to prove that two doses of the vaccine protects 95% of those vaccinated people against becoming seriously ill, is to expose, for example, 1000 people to the virus and then discover that less than 50 of them became seriously ill. According to the Pfizer-BioNTech trial data (see the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) Briefing document on the Pfizer-BioNTech vaccine - https://www.fda.gov/media/144245/download), which is where the 95% value originates, the

trial did not examine who had been exposed to the virus, it merely looked at who became ill, so it is not possible to say what proportion of people were actually protected from becoming ill. All that can be said, and all that the authors of the study did say, is that the vaccine has an efficacy of 95%.

A 95% vaccine efficacy value means that, relative to the unvaccinated group, 95% fewer people in the vaccinated group became infected. The 95% figure is not an absolute amount – that is, the research did not show that 95% of people who receive both doses of the vaccine will be protected against becoming seriously ill, as stated in the advertisement. Vaccine efficacy is a relative risk reduction value.

The World Health Organisation have a useful explanation of vaccine efficacy at https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection which includes this statement:

> "*So, for example, let's imagine a vaccine with a proven efficacy of 80%. This means that – out of the people in the clinical trial – those who received the vaccine were at a 80% lower risk of developing disease than the group who received the placebo. This is calculated by comparing the number of cases of disease in the vaccinated group versus the placebo group. An efficacy of 80% does not mean that 20% of the vaccinated group will become ill.*"

Clearly, the final sentence could just as easily read "*An efficacy of 80% does not mean that 80% of the vaccinated group will not become ill*".

The problem with treating a relative value as if it were an absolute value is that it no longer accounts for the fact that there was a very large percentage of people who were unvaccinated who also did not become ill. The statement *"Studies have shown that 95% of people who received both doses of the vaccine were protected against getting seriously ill"* misleads the reader into thinking that 95 out of 100 people who receive both doses of the vaccine will not become seriously ill. In other words, the advertisement incorrectly implies that the risk of infection with COVID-19 after receiving two doses of the vaccine is 5%.

Vaccine efficacy is an indication of how well a vaccinated group does with respect to a certain outcome (in this case, how well it protects against illness) compared to how well an unvaccinated group performs in relation to that same outcome. Here is the data from the Pfizer-BioNTech trial, as outlined in the article that I referred to in my Complaint (https://www.nytimes.com/2020/12/13/learning/what-does-95-effective-mean-teaching-the-math-of-vaccine-efficacy.html):

Group	**Group Size**	**Number Infected**	**Infection risk**
Placebo	21,830	162	$\frac{162}{21830}$ =0.74%
Vaccine	21,830	8	$\frac{8}{21830}$ =0.04%

It should be noted that the actual risk of infection after receiving the vaccine was 0.04% (i.e., 99.96% of the vaccine group did not get ill). However, over 99% of the placebo group also did not get ill. The absolute risk reduction due to the vaccine was only 0.7%.

Because it is not known how many of the vaccine group or how many of the placebo group were actually exposed to the virus, it is not possible to specify a number or a percentage of people that were actually protected by the vaccine. So instead, vaccine efficacy is the result of a calculation that takes into account the relative risk of illness between the two groups. The 95% (vaccine efficacy) figure that is used in the advertisement is calculated as follows:

$$\frac{Reduction\ in\ risk\ in\ vaccine\ group}{Risk\ in\ placebo\ group} = \frac{(0.74\% - 0.04\%)}{0.74\%} = 95\%$$

To reiterate, the 95% figure is not the percentage of people that were protected against getting ill after receiving two doses, as advertised. The 95% figure simply means that, compared to the placebo group, 95% fewer people became ill after receiving two doses of the vaccine, and it is completely unknown how many people in the study actually came into contact with the virus.

The statement in the advertisement purports to show an absolute risk reduction of 95% as a result of the vaccine. As I have explained, if absolute risk is to be discussed, then both the vaccine and the placebo groups had over 99% of people with no cases, and the vaccine group had an absolute risk reduction of only 0.7% relative to the placebo group. If, on the other hand, the advertiser wishes to discuss relative risk, then the 95% value could be used but it should be made clear that, in the trial (rather than the real world), 95% fewer people became ill after receiving two doses of the vaccine. This on its own would still be misleading, however because, in context, that 95% reduction was from an already very low risk of 0.74% to a risk of 0.04%.

Additional Complaint

The statement that I objected to in the advertisement refers to vaccine recipients being "protected against getting seriously ill". This is untrue.

In the Pfizer-BioNTech trial (see page 14 of the VRBPAC Briefing document), the case definition for a confirmed COVID-19 case was the presence of at least one of the following symptoms and a positive SARS-CoV-2 test within 4 days of the symptomatic period:

- Fever
- New or increased cough
- New or increased shortness of breath
- Chills
- New or increased muscle pain
- New loss of taste or smell
- Sore throat
- Diarrhea (sic.)
- Vomiting
- Fatigue
- Headache
- Nasal congestion or runny nose
- Nausea

The above table that I used to calculate the 95% vaccine efficacy value summarises confirmed cases that had at least one of the above symptoms and a positive test. That is, the 95% efficacy value was generated based on non-serious illness, not on serious illness as stated in the advertisement.

The trial also provided a case definition of a "severe COVID" case (i.e., serious illness) with at least one of the following:

- Clinical signs at rest indicative of severe systemic illness (RR ≥ 30 breaths per minute, HR ≥ 125 beats per minute, SpO2 ≤ 93% on room air at sea level, or PaO2/FiO2 < 300 mm Hg)
- Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)
- Evidence of shock (SBP < 90 mm Hg, DBP < 60 mmHg, or requiring vasopressors)

- Significant acute renal, hepatic, or neurologic dysfunction
- Admission to an ICU
- Death

The severe COVID-19 occurrences are itemised in two tables on page 31 of the VRBPAC Briefing document and are summarised below:

Group	**Severe case ≥ 7 days after dose 2**	**Vaccine efficacy**
Placebo	3	66.4%
Vaccine	1	

Group	**Severe case after dose 1**	**Vaccine efficacy**
Placebo	9	88.9%
Vaccine	1	

That is, the claim that the 95% (vaccine efficacy) value relates to cases of "serious illness" is not supported by the results of the Pfizer-BioNTech trial. The 95% value relates to non-serious illness only. If the advertisement was to correctly describe vaccine efficacy after two doses of the Pfizer-BioNTech vaccine, as calculated in the Pfizer-BioNTech trial study, then the 95% value would need to be replaced by a value of 66.4%.

Comments in relation to the two articles cited in the Decision

The Decision also refers to two New England Journal of Medicine articles that were provided by the advertiser and apparently "support[ed] the claim that 95% of people who received both doses of the vaccine were protected from getting seriously ill".

That is not correct and has obviously affected the Decision. Looking at those articles in turn:

1. "*Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine*" - 31 December 2020

The Decision highlights the statement "*A two-dose regimen of BNT162b2 conferred 95% protection against Covid-19 in persons 16 years of age or older*.".

It will be appreciated from my above comments that the value of 95% itself is not disputed. However, the quoted passage from this article does not support the claim in the advertisement that 95% of people who received both doses of the vaccine were protected against getting ill, and it certainly does not refer to serious/severe illness. The authors of this article were well aware that the 95% value related to vaccine efficacy (see "*This case split corresponds to 95.0% vaccine efficacy*") and were also aware of the way in which vaccine efficacy is calculated.

The quote also restricts the 95% value to persons 16 years of age or over, which is in keeping with the trial data. The advertisement also does not make this clear.

2. "*BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting*" - 15 April 2021

The Decision highlights the statement "*This study estimates a high effectiveness of the BNT162b2 vaccine for preventing symptomatic Covid-19 in a noncontrolled setting, similar to the vaccine efficacy reported in the randomized trial. Our study also suggests that effectiveness is high for the more serious outcomes: hospitalization, severe illness, and death*."

It is firstly noted that the 95% value is not mentioned in this passage so this passage clearly cannot support the statement in the article. But the word “effectiveness” is used. As explained in the WHO article mentioned above, vaccine effectiveness is a measure of how well a vaccine performs in the real world, whereas vaccine efficacy is a measure of vaccine performance in a controlled trial. So the cited article “estimates” that the vaccine will perform similarly to the vaccine efficacy results calculated in the trial in relation to symptomatic (i.e., non-serious) infection, and “suggests” that the vaccine will perform well for more serious outcomes. This quote therefore merely “estimates” and “suggests” that the vaccine will perform well in real world situations. It does not support the statement made in the advertisement.

Furthermore, although the quote from this second article refers to “serious outcomes”, it does not support the claim in the advertisement that the 95% value is associated with “serious illness”. As mentioned above, the Pfizer-BioNTech trial did look at severe/serious illness, but there were far fewer severe cases than non-serious illnesses (bringing into question their statistical significance), and the vaccine efficacy in relation to those severe illnesses was less than the 95% value quoted in the advertisement.

Appendix 4

CHAIRPERSON OF THE APPEAL BOARD ACCEPT RULING

SUMMARY

The Chair of the Complaints Board ruled on 2 August 2021 the complaint regarding a New Zealand Government newspaper advertisement about the COVID-19 vaccination campaign had no grounds to proceed.

The Complainant appealed the Decision. The appeal application was considered by the Chairperson of the Appeal Board.

The Chairperson ruled that the appeal application be accepted, parties be provided the opportunity to comment, and the matter be referred to the Complaints Board.

CHAIRPERSON’S RULING

The Chairperson viewed the application for appeal. She noted that there were five grounds upon which an appeal was able to proceed. These were listed at Clause 6(c) of the Second Schedule of the Advertising Standards Complaints Board Complaints Procedures and were as follows:

(a) The proper procedures have not been followed.

(b) There is new evidence of sufficient substance to affect the decision.

(c) Evidence provided to the Complaints Board has been misinterpreted to the extent that it has affected the decision.

(d) The decision is against the weight of evidence.

(e) It is in the interests of natural justice that the matter be reheard.

The Complainant appealed the Decision from the Chair of the Complaints Board which ruled the complaint had No Grounds to Proceed.

After reviewing all the relevant correspondence, the Chairperson held that on balance the Appeal application had met the threshold to establish grounds for appeal under Ground (c), evidence provided has been misinterpreted to the extent that it has affected the decision.

Accordingly, the Chairperson ruled the Appeal application be accepted, parties be provided the opportunity to comment, and the matter be referred to the Complaints Board.

Chairperson's Ruling: Appeal application Accepted

Appendix 5

INITIAL RESPONSES FROM ADVERTISER, DEPARTMENT OF THE PRIME MINISTER AND CABINET

Re: New Zealand Government Print – Appeal 21/014

Thank you for your email of 19 October 2021 in which you ask for the Department of the Prime Minister and Cabinet's response to complaints received about our Vaccine press advertisement.

Attached is the advertisement which ran in press in all daily and provincial papers on 29th and 30th May. Please see the list of papers in Appendix A attached.

You have indicated that the concerns of the complaints fall under the following areas:

Advertising Standards Code - Principle 2, Rule 2(b) Truthful Presentation, Rule 2(e) Advocacy

You've also indicated that the Complaints Board deliberation will focus on the following statement:

"Studies have shown that 95% of people who received both doses of the vaccine were protected against getting seriously ill."

This statement ran again in press advertising on 5th June and 12th June. Since then, we have clarified the first part of the statement to read: "*In the clinical trials it was found that the Pfizer vaccine gave 95% protection against…"*.
This has been amended across our collateral.

With regards to the complainant's objection to the phrase "protected against getting seriously ill", evidence both at the time of the advertisement and since supports that the Pfizer vaccine protects against serious illness. The content included in the advertisement was a reasonable reflection of the evidence at the time for the effectiveness of the vaccine, communicated for a general readership. Data on COVID-19 and of the effectiveness of the vaccines has continued to emerge over the course of the pandemic. The evidence at the time of the advertisement included but extended beyond that from clinical trials, as referenced below.

At the time of the advertisement in May 2021, key data on the Pfizer vaccine included the results of the clinical trials (Polack et al, 2020) conducted as part of vaccine development but also new and emerging evidence from studies of vaccine effectiveness throughout overseas vaccine rollout (such as Dagan et al, 2021; Hall et al, 2021; Levine-Tiefenbrun et al, 2021).

The clinical trial by Polack et al. found that two doses of the Pfizer vaccine were 95% effective against COVID-19 (95% Confidence Interval (CI), 90.3-97.6). Among the 10 cases of severe COVID-19 that occurred in the trial, only 1 occurred in the vaccine group, however estimating protection against severe disease was a secondary objective of this clinical trial. Severe COVID-19 is defined by the FDA as confirmed COVID-19 with one of the following additional features: clinical signs at rest that are indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death.

The 'studies' referred to in the advertisement would have drawn on observational studies, which at the time of the advertisement and since have shown that the Pfizer vaccine protects against serious illness, and severe COVID-19. A large observational study conducted in Israel and reported in April 2021 demonstrated the Pfizer vaccine was 92% (95% CI, 75-100) effective against severe COVID-19 disease after two doses, and 87% (95% CI, 55-100) effective against hospitalisation (Dagan et al, 2021). The effectiveness of the vaccine against severe disease and hospitalisation has continued to be demonstrated in studies, even in the presence of Delta, for example, see Stowe et al. (2021) and Bernal et al. (2021). While observational studies are often prone to confounding, the robust design of the studies and statistical analysis, as well as their convergence on a similar finding provide reassurance. Furthermore, our technical expert advice, as ascertained through the COVID-19 Vaccine Technical Advisory Group have continually pointed us to utilise these studies as reliable sources of evidence.

Vaccine protection against severe disease has been demonstrated to be generally higher than against mild disease. This has also been demonstrated for diseases other than COVID-19 and is well-recognised knowledge in medicine which also informs interpretation of evidence as discussed in the BMJ (Dean & Madewell, 2021). For example, efficacy of an inactivated influenza vaccine against flu of any severity was 55.4% (95% CI, 39.1 to 67.3%), but efficacy against moderate-to-severe disease was higher at 73.1% (95% CI 47.1 to 86.3%). Similar relationships have been observed for dengue, pertussis, malaria, varicella, and cholera vaccines.

Appendix 6

ADDITIONAL QUESTIONS FROM THE ASA SECRETARIAT TO THE ADVERTISER

Thank you for your response dated 1 November 2021. We note the response mainly focuses on the wording in the statement relating to "getting seriously ill".

In preparing the papers for the Complaints Board to consider Complaint 21/330, Appeal 21/014, it would be helpful to receive some additional comments on a matter raised by the Complainant.

Part of the Complainant's argument appears to be around two different measurements that we understand are commonly used with vaccines; relative risk reduction (RRR) and absolute risk reduction (ARR).

Our interpretation of the complaint is that the Complainant does not dispute the vaccine efficacy value of 95% per se, but disputes the way the statement is written as a misinterpretation of the clinical data provided by the Advertiser in response to Complaint 21/229. I have attached a copy of Decision 21/330 that refers to this information.

Could you please provide responses to the questions below:

Is the statement in the advertisement technically correct?

Is it possible the statement may lead the consumer to believe something different from what the clinical data shows (if you take into account ARR)?

Is the statement a true reflection of the clinical trial data?

What does the Advertiser consider the likely consumer take-out of the statement to be?

Appendix 7

ADDITIONAL RESPONSE TO ASA QUESTIONS FROM THE ADVERTISER AND MEDSAFE

See response from Medsafe below:

The information we have was as provided in the clinical data package from Pfizer. A summary is reflected in the medicine datasheet which is published on the Medsafe website at: https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf

Is the statement in the advertisement technically correct?
The most relevant wording is from pages 9 – 12 of the data sheet. Table 5 is very relevant as is a specific efficacy update on severe COVID (95% after dose 2).

Is it possible the statement may lead the consumer to believe something different from what the clinical data shows (if you take into account ARR)?
Not in our opinion

Is the statement a true reflection of the clinical trial data?
See datasheet above, the medicine datasheet is a summary of the known benefits and risks of the vaccine, as approved by Medsafe.

And this last question is a response from the advertising team, as Medsafe is not the Advertiser:

What does the Advertiser consider the likely consumer take-out of the statement to be?
Likely consumer outtake of the statement *"Studies have shown that about 95% of people who received both doses of the vaccine were protected against getting seriously ill"* is likely to be that the vaccine is highly effective in protecting people from getting seriously ill from COVID-19.